DEPARTMENT of HEALTH and HUMAN SERVICES

Fiscal Year 2014

Food and Drug Administration

Justification of Estimates for Appropriations Committees

Message from the FDA Commissioner

I am pleased to present the Administration's FY 2014 budget request for the Food and Drug Administration (FDA). This budget will enable FDA to sustain and expand its mission of protecting and promoting the health and well-being of the American people, in the face of dramatic scientific advancements and market-based changes—from personalized medicine and nanotechnology to the globalization of our food and medical product supplies.

FDA plays a vital role in the health of our citizens and our regulated industries. FDA oversees the safety of most of America's food supply, the safety and effectiveness of drugs, biologics, and medical devices, the purity of the blood supply, the development of medical countermeasures, the safety of animal feed as well as the safety and effectiveness of drugs for use in livestock, pets, and other animals, cosmetics, dietary supplements, and most recently, reducing harm from tobacco use. Together, the products we regulate represent over 20 cents of every consumer dollar spent on products in the United States.

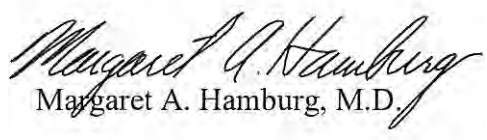
FDA is a good bargain – we have used your investments wisely, delivering results that help Americans every day. We carry out our broad public health responsibilities effectively and with few taxpayer dollars. Their return on investment is high: they get assurance that the food they serve their families every day is safe to eat, access to life-saving medicines fast or faster than anywhere in the world, and confidence that the medical products they rely on, from toothpaste to cancer drugs to artificial organs, will provide the health benefits they expect. As all of our budgets are tightened, we are doing our part to target program and infrastructure spending to maximize the impact of every dollar, and to find savings where we can.

Even as FDA continues to safeguard America's food and medical products effectively and efficiently, our job has become increasingly demanding. The science we need to do our job effectively is evolving at a dizzying pace, and the supply chains we oversee continue to grow in scope and complexity. Congress has continued to expand our responsibilities through new legislation. In the Food Safety Modernization Act (FSMA) and the FDA Safety and Innovation Act (FDASIA), Congress has charged us with significant new responsibilities:(1) to modernize this nation's food safety system and improve the safety of imported food; and (2) to bring innovative medical products swiftly to the American people and strengthen protection of the global drug supply chain. We are mindful that we are your partners in carrying out these policies

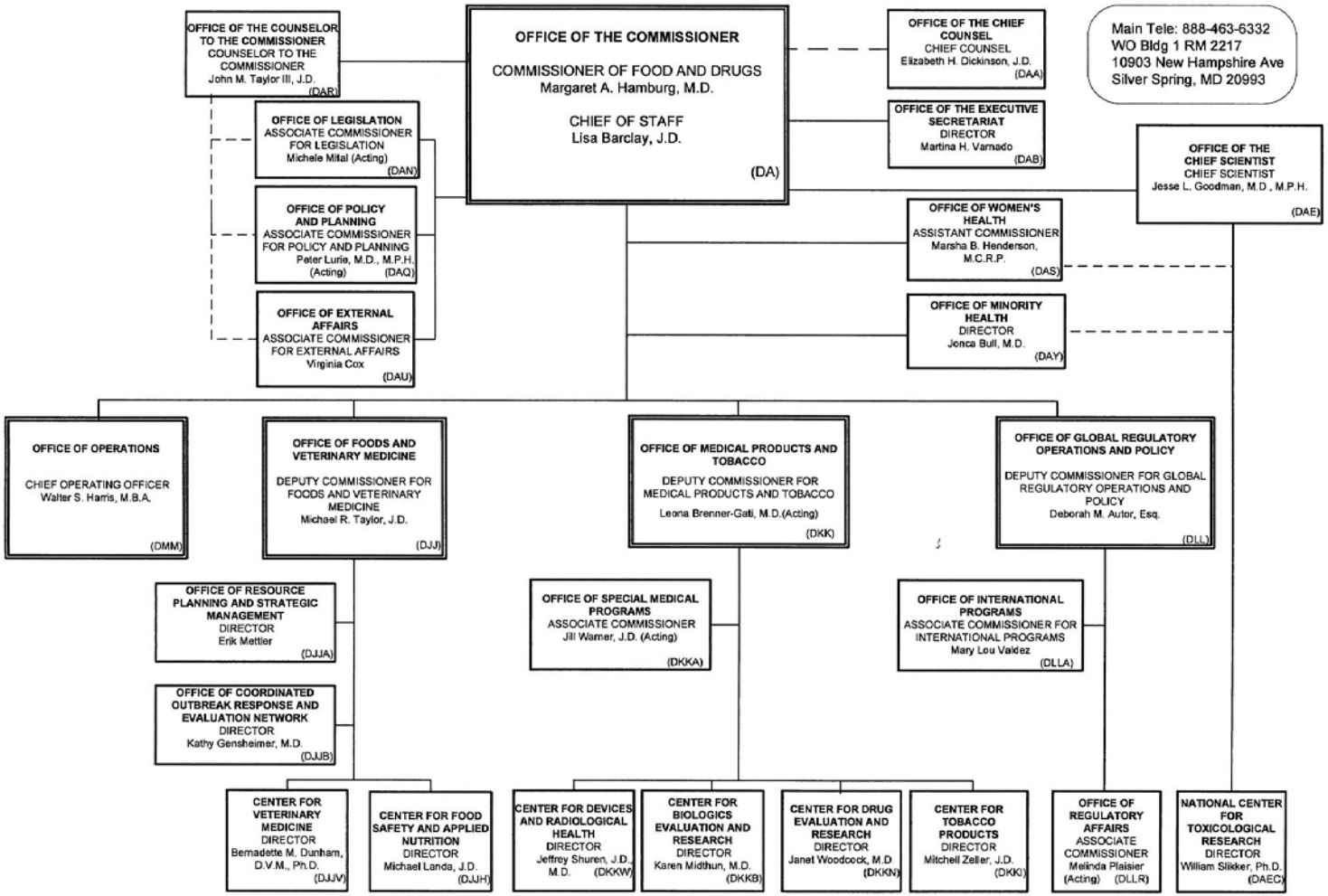
FDA's FY2014 Budget. In the attached budget, we are seeking targeted increases to fulfill our end of the partnership and deliver on the promise of FSMA and FDASIA for the American people. The budget request is $4.7 billion, an increase of $821 million, or 21 percent, over FY 2012. The budget includes investments to (1) accelerate implementation of FSMA, (2) modernize regulatory science and support implementation of FDASIA, in part through the new laboratory at White Oak and upgrades to other facilities, and (3) to strengthen FDA's global oversight capacity and enhance trade with China, by improving the safety of foods and medical products imported into the United States. It also includes public health activities to decrease initiation of tobacco use and encourage cessation, and work to advance medical counter measures. In addition, the

enactment of FDASIA reauthorized and established new users fee programs that will advance the safety of the nation's drug and medical products supply. With these funds, we will be better positioned to spend our resources more effectively by preventing food contamination (rather than just responding after it occurs), and by actively supporting industry efforts to innovate products that benefit Americans' health.

We look forward to working with you as we build the foundations of a modern, global-facing, science-based public health agency, and continue to transform FDA for the new century.



FOOD AND DRUG ADMINISTRATION



Vanwood Stanley 3/4/13

Approved by the FDA Reorganization Coordinator
and Principal Delegation Control Officer

Food and Drug Administration
FY 2014 Congressional Budget Request
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Executive Summary

Statement of FDA Mission

FDA is responsible for protecting the public health by ensuring the safety, effectiveness, and security of human and veterinary drugs, biological products and medical devices; ensuring the safety of foods, cosmetics, and radiation-emitting products; and regulating tobacco products.

FDA is also responsible for advancing the public health by helping to speed innovations that make medicines more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medicines and foods to maintain and improve their health. FDA also has responsibility for regulating the manufacturing, marketing and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.

FDA also plays a significant role in the Nation's counterterrorism capability. FDA fulfills this responsibility by ensuring the security of the food supply and by fostering development of medical products to respond to deliberate and naturally emerging public health threats.

The Scope of Our Mission is Vast and Complex

FDA plays a vital role in the health of our citizens and our regulated industries. Congress has given FDA responsibility for a vast range of products that are central to the health and well-being of every American. FDA oversees the safety of most of America's food supply, the safety and effectiveness of drugs, biologics, and medical devices, the purity of the blood supply, the development of medical countermeasures, the safety of animal feed as well as the safety and effectiveness of drugs for use in livestock, pets, and other animals, and most recently, reducing harm from tobacco use. Together, the products we regulate represent over 20 cents of every consumer dollar spent on products in the US. Public trust in FDA oversight breeds confidence in our regulated industries, at home and in the global market place.

A strong FDA is critical not only to the public health, but to the United States economy, the balance of trade, and homeland security. Our work has ripple effects on innovation in the industries we regulate and on costs in the broader economic and health care system. For example, on January 16, 2013, FDA proposed regulations on manufactured food and produce safety that outline new, innovative means for ensuring that a factory or warehouse's food is safe and for eliminating potential contamination of fruits and vegetables. FDA estimates that the cost of foodborne illnesses associated with FDA-regulated foods covered by these two rules is nearly $4 billion per year. The proposed rule for produce safety alone is estimated to reduce illnesses by $1 billion annually.

FDA is a Bargain

Every American pays about $8 per year for the vast array of protections and services FDA provides. The return on this investment is remarkable. For this amount, FDA assures that the food that Americans serve their families every day is safe to eat and that Americans have access to life-saving medicines that are approved as fast or faster than anywhere in the world. For this amount, Americans can have confidence that the medical products that they rely on, ranging from toothpaste to cancer drugs to artificial organs, will provide the expected health benefits. FDA is a sound investment for the American people.

FDA Delivers Results

FDA is delivering significant, quantifiable, results that help Americans every day. FDA's drug approval system continues to lead the world in both quality and speed. In FY 2012, for the second year in a row, FDA approved 35 novel medicines. About 75% of those drugs were approved by FDA before any other country in the world. Among the FY 2012 approvals was a groundbreaking treatment for cystic fibrosis, approved in only 3.5 months, and the first drugs to treat advanced basal cell carcinoma and bone marrow disease. FDA prevented 282 drug shortages in 2012 and cut in half number of shortages in the prior year. FDA achieved significant reductions in medical device application review times and application back logs. FDA issued the first two new major proposed rules to implement the Food Safety Modernization Act, rules on preventive controls for human food and produce safety, so we can prevent contamination rather than respond to adverse events after they occur.

We are finding ways to leverage our scarce resources, through both domestic and global collaborations, ranging from partnering with foreign governments to improve the quality of imports to the United States, to partnerships with the nonprofit Medical Device Innovation Consortium to work on regulatory science initiatives.

The Scope of FDA Mission is Evolving Rapidly

We are in the midst of dramatic technological and market-based changes. The food and drug supply chains we oversee are not only increasingly global, but increasingly complex. The scientific underpinnings of the products we regulate are advancing at a dizzying pace — from personalized medicine and nanotechnology to tissue engineering and vaccine manufacturing. We must harness new science and technology so that we can be active partners with American industries to accelerate medical innovation.

To address these challenges, we are partners with Congress in implementing significant new authorities to safeguard America's food supply, modernize medical product safety and innovation, and reduce the harms of tobacco use. These new authorities reposition FDA on key fronts. The Food and Drug Administration Safety and Innovation Act (FDASIA) is intended to increase the speed and predictability of medical product review

while enhancing safety and fostering innovation, and better protect the drug supply chain. FDASIA also established two new user fee programs that will bring more affordable therapies to patients. FSMA creates a modern food safety system based on prevention. The Family Smoking Prevention and Tobacco Control Act provides FDA with new authorities to address one of the most important preventable public health problems. The Biologics Price Competition and Innovation Act, part of the Patient Protection and Affordable Care Act, established a new regulatory pathway for biosimilar biologic products. Together with ongoing initiatives to advance regulatory science and innovation and to transform FDA into a globally-facing regulatory authority, these Acts establish the foundations of a modern, science-based public health agency.

These changes are driving us to stretch our limited resources and find innovative, global-facing approaches to preserving the safety and quality of our nation's food and medical product supplies. These changes also drive our budget request for FY 2014 – carefully targeted investments to support food safety and FSMA implementation, medical product innovation and FDASIA implementation, and to build agency capacity for oversight of the global supply chain.

FDA FY 2014 Budget Request

Overview

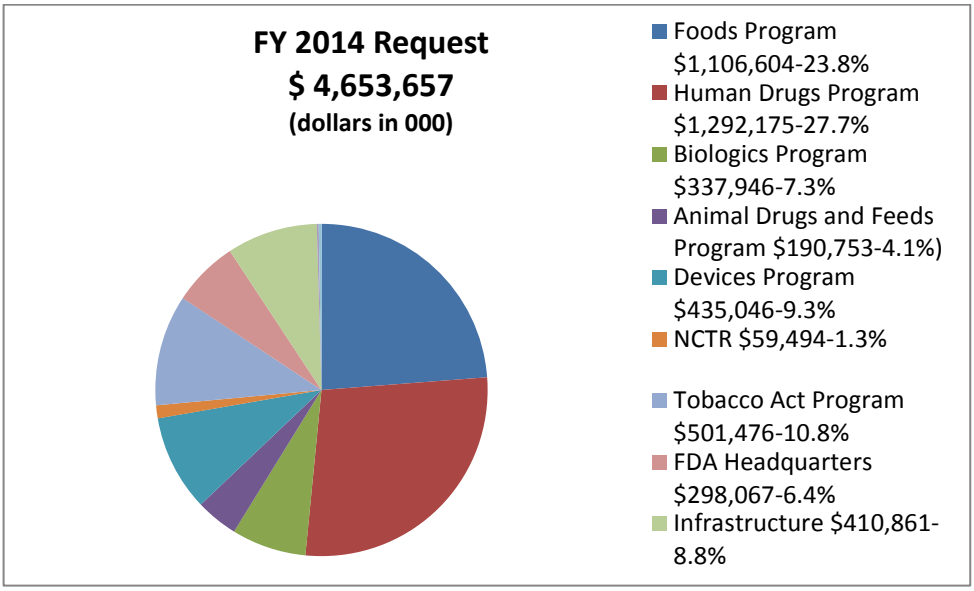
The fiscal year (FY) 2014 President's Budget request for FDA is $4,653,657,000 comprised of $2,557,693,000 in budget authority and $2,095,964,000 in total user fees.

The FY 2014 budget request provides a total program level increase of $821,453,000 above the amount enacted into law for FY 2012 distributed between a budget authority increase of $51,884,000 and a total user fee increase of $769,569,000. The user fee increases are $269,434,000 for proposed new user fees, $175,510,000 for current law user fees, and $324,625,000 for indefinite user fees.

The following table summarizes the FDA budgets for fiscal years 2012, 2013 and 2014.

FY 2014 Overview Food and Drug Administration (Dollars in thousands)					
	FY 2012 Enacted	**FY 2012 Actuals**	**FY 2013 CR**	**FY 2014 Request**	**+/- FY 2012 Enacted**
Total	**$3,832,204**	**$3,556,161**	**$4,183,570**	**$4,653,657**	**$821,453**
Budget Authority	$2,505,809	$2,506,553	$2,521,145	$2,557,693	$51,884
User Fees	$1,326,395	$1,049,608	$1,662,425	$2,095,964	$769,569
FTE	**13,496**	**13,382**	**14,416**	**15,424**	**1,928**

The distribution of the FY 2014 Request by programs is illustrated in the following chart.



Priority Investments

In an increasingly global economy, and facing revolutionary advances in science and technology, FDA must modernize and transform operations to address the emerging needs of the 21st century. We envision a transformed and integrated global food safety system, focused on prevention and improved nutrition. We envision patients and families benefiting from decades of investment in medical science and technology. We also envision a strong foundation of regulatory science to support FDA efforts to ensure the safety and effectiveness of new medical products throughout their life cycles.

1. Transforming Food Safety

Budget Authority: +$43,410,000 / +59 FTE
User Fees: +$252,269,000 / +548 FTE

FDA will use the resources in this initiative to build prevention-focused domestic and import food and feed safety systems that implement FSMA authorities and oversight tools. These investments will provide industry with consistent and transparent food and feed safety guidance to assure the safety of America's food and feed supply. This investment is modest compared to the economic value it can deliver: reduced costs to industry, government, and the health care system due to less foodborne illness. Currently 48 million foodborne illnesses occur each year, resulting in an estimated 128,000 hospitalizations and 3,000 deaths. The average cost per case of foodborne illness is estimated at $1,626 – more than $78 billion per year.

2. Medical Product Innovation and FDASIA implementation

2a. Current Law User Fees +$500,135,000 / 1,248 FTE

The User Fee programs allow FDA to fulfill its mission of protecting the public health and accelerating innovation in the industry. The fees collected are used to support the review and surveillance of human and animal drugs, medical and mammography devices, color additives, exports, and tobacco products. Approximately $2.5m of the Current Law User Fee increases are for Transforming Food Safety activities.

Existing user fee laws authorize user fee increases for many of the FDA user fee programs. These requested increases would expand the available options for treating and curing diseases and addressing other important public health needs.

2.b. White Oak Consolidation
Budget Authority: +$17,658,000 / 0 FTE
User Fees: +283,000 / 0 FTE

Supportive of FDA's public health mission, Congress directed FDA and GSA to construct up-to-date facilities for FDA to carry out cutting-edge research to ensure that FDA is providing the best possible oversight over its regulated products to protect the American public. The requested funds are needed to support the outfitting and required certification and operation of the two largest laboratories – Buildings 52 and 72, the Life Sciences-Biodefense Complex (LSBC) and the expansion of the vivarium (Complex) to be completed and be ready for occupancy in FY 2014.

These funds will be the last leg of a $300 million investment that will enable FDA to properly equip and operate the LSBC and begin occupancy and utilization of the Complex. The lab is largely complete; these funds support final build-out and the certifications needed for occupancy. Failure to make this final, small investment will delay the return on investment on this facility and place FDA's substantial prior investment in this facility in jeopardy.

2.c. Medical Countermeasures (MCMi)
Budget Authority: +$3,510,000

According to the U.S. intelligence community, chemical, biological, radiological and nuclear (CBRN) weapons and emerging infectious diseases present real, substantial and growing threats to the national security of the United States.

MCMi supports important national security and public health priorities. Through the MCMi, FDA is helping to ensure that Americans have access to the medicines and vaccines they need to counter a deliberate CBRN attack or a naturally occurring epidemic.

Funding this initiative will support a strong FDA workforce with enhanced expertise in CBRN issues, faster development and availability of MCMs, a more resilient Nation that is better able to cope with the CBRN and infectious disease threats, and stronger national security.

3. Oversight of the global supply chain- Safety Inspections in China
Budget Authority: +$10,000,000 / 19 FTE

FDA will strengthen the supply chain for foods, drugs, and ingredients manufactured in China. The China Initiative, in which we work with Chinese industry and train our regulatory counterparts in China, is essential to improving the safety of exports from this vast country. Although we will increase the number of inspectors based in China, FDA cannot assure the safety of the huge and

growing number of Chinese exports through inspections alone. Through this initiative, Chinese regulators will enhance their understanding of FDA requirements and strengthen their own capacity to assure the safety of the food and drugs that their industries export to the United States

The result will be fewer import safety emergencies, less foodborne illness and earlier identification of safety problems associated with foods, drugs, and ingredients manufactured in China.

Details of the FDA FY 2014 Initiatives

The FDA Congressional Budget Justification contains business case papers justifying the funding increases described above. Within each business case paper, FDA identifies the need for the FY 2014 funding, the activities that FDA will conduct, and the performance that FDA will achieve.

Overview of Performance

In April 2011, FDA published its five year strategic plan, "Strategic Priorities 2011 – 2015." (http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm227527.htm)
In that document, we laid out the mission-critical areas of focus for modernizing the agency, and committed to using the following cross-cutting priorities to "improve agency infrastructure, modernize regulatory processes, strengthen our workforce—and, ultimately, better promote and protect the health of the American people."

- Advance Regulatory Science and Innovation
- Strengthen the Safety and Integrity of the Global Supply Chain
- Strengthen Compliance and Enforcement Activities to Support Public Health
- Expand Efforts to Meet the Needs of Special Populations
- Advance Medical Countermeasures and Emergency Preparedness.

These goals and objectives provide the vehicle for focusing agency efforts to achieve FDA's public health mission and to fulfill FDA's role in supporting the larger mission and strategic goals of HHS. Our budget requests since that time have focused on these priorities and principles, and this FY 2014 budget request continues building FDA capacity in these key areas.

Mapping FDA's FY2014 Budget Request to the Agency's Strategic Priorities and Principles

The following table maps this year's budget request to the priorities and principles in FDA's "Strategic Priorities 2011 – 2015."

FDA Strategic Priorities FDA FY2014 Budget Request Priorities	Advance Regulatory Science and Innovation	Strengthen the Safety and Integrity of the Global Supply Chain	Strengthen Compliance and Enforcement Activities to Support Public Health	Expand Efforts to Meet the Needs of Special Populations	Advance Medical Countermeasures and Emergency Preparedness
1. Transforming Food Safety	X	X	X		
2.a. FDASIA Implementation, User Fees	X	X	X	X	
2.b. White Oak Consolidation	X				X
2.c. Medical Countermeasures	X				X
3. Oversight of the global supply chain- Safety Inspections in China	X	X	X		

The business case papers in the following Budget Justification include the specific work we propose in each area, and demonstrate the strong alignment of this Budget Request with our strategic priorities. For example, our budget request for Safety Inspections in China includes work not only to Strengthen the Safety of the Global Supply Chain, it also includes regulatory science work to improve risk modeling. Medical Countermeasure science is a key focus of the initial work slated for the new laboratory ("White Oak Consolidation"). The budget request for PDUFA user fees ("FDASIA Implementation") includes work to advance the development of drugs for rare diseases. Funds requested for the new generic drug program ("FDASIA Implementation") will also enhance global supply chain safety by requiring that generic drug facilities and sites around the world self-identify.

Performance Management Overview: Transparency and Accountability

FDA-TRACK is the agency-wide performance management system that FDA launched in April 2010. FDA-TRACK monitors, analyzes and reports monthly performance on all FDA program offices and on key cross-cutting initiatives. Each quarter, the FDA-TRACK team uses statistical models to analyze monthly performance data collected from each office and initiative. Face-to-face briefings are then conducted with each program office whereby the responsible office directors present their performance data and results to the FDA executive leadership. These briefings stimulate discussion and facilitate better communication, decision-making, plan of action and ultimately, performance. Briefing summaries and performance results are then posted to the FDA-TRACK website, allowing FDA's stakeholders to monitor progress on more than 600 performance measures and 100 key projects.

The objectives of FDA-TRACK can be explained through its name:

- **T**ransparency – provides interested parties an unprecedented look into how FDA performs its work.
- **R**esults – highlights performance measures and results with relevance to the agency's public health mission.
- **A**ccountability – requires senior managers to develop, track, and report performance measures that will improve the agency's accountability to the public; holds the program offices accountable for their priorities, plans and results.
- **C**redibility – encourages sharing of information about FDA performance which is essential for the agency's credibility; provides the opportunity to submit suggestions which will be considered as part of the continuous improvement efforts.
- **K**nowledge-sharing – enables the identification of common issues and interdependencies among program offices to improve FDA's operational effectiveness through better collaboration and sharing of ideas.

The performance measures in FDA-TRACK represent the foundational activities and outputs produced by our employees. To better express how these activities and outputs contribute to our overall public health mission, an effort is in place to align each FDA-TRACK measure to the program's strategic plan and objectives. This alignment will provide even greater opportunities for FDA's leadership to make clear and data-driven decisions based on performance.

Since the inception of FDA-TRACK, FDA has seen significant performance improvement in many of our programs, including the elimination of the backlog of generic new animal drug applications and increases in hospital participation in the MedSun Program. From the operational-side, FDA has dramatically improved its advisory committee vacancy rate and progressed to dramatically reduce its Freedom of Information Act (FOIA) backlog. FDA-TRACK has enabled better performance by providing a medium to track progress, monitor results, discuss concerns and communicate achievement.

The FDA-TRACK website averages over 75,000 visits each quarter and over 22,000 monthly subscribers.

Advancing Medical Countermeasures
FDA Medical Countermeasures Initiative
Budget Authority: +$3,510,000

The following table displays the FDA budget authority for the Medical Countermeasures Initiative in the FY 2014 Congressional Budget Justification.

Advancing Medical Countermeasures

(Dollars in Millions)

Program	FY 2010/FY 2011 $170m One-Time Allocation (non-add)[1]	FY 2012 Enacted	FY 2014 Request	+/- FY 2012 Enacted
Budget Authority:				
Human Drugs	**$28.017**	**$4.756**	**$5.596**	**$0.840**
Center	27.144	4.756	5.596	0.840
Field Activities	0.873	0.000	0.000	0.000
Biologics	**$27.362**	**$1.974**	**$2.226**	**$0.252**
Center	26.489	1.974	2.226	0.252
Field Activities	0.873	0.000	0.000	0.000
Devices and Radiological Health	**$17.099**	**$2.997**	**$3.720**	**$0.723**
Center	16.661	2.997	3.720	0.723
Field Activities	0.438	0.000	0.000	0.000
FDA Headquarters	**$90.234**	**$9.013**	**10.312**	**1.299**
Other Rent and Rent Related	**$2.603**	**$0.472**	**0.868**	**0.396**
GSA Rental Payments	**$4.685**	**$0.826**	**0.826**	**0.000**
Total Advancing Medical Countermeasures	**$170.000**	**$20.038**	**$23.548**	**$3.510**

[1] Under the August 20, 2010, budget amendment and a related announcement by Secretary Sebelius, FDA received $170 million from amounts appropriated under Public Laws 111-8 and 111-117. Under the terms of Public Law 112-10 (April 15, 2011), FDA can spend the $170 million on activities related to chemical, biological, radiological and nuclear threats, in addition to the previous authority to spend these funds on emerging infectious diseases.

1. Initiative Summary:

The FDA Medical Countermeasures Initiative (MCMi) is designed to meet America's national security and public health requirements for medical countermeasure (MCM) readiness. In advance of Congress' FY 2012 appropriation for the MCMi, FDA received an allocation of one-time funding at the close of FY 2010 to immediately commence MCMi activities. With these funds, FDA established a base program at its current operating level of 77 FTE.

The FY 2014 budget contains resources that will allow FDA to sustain the current level of staffing and activities for the MCMi. With these FY 2014 resources, FDA will support partnerships with industry, academia, and government partners to improve MCM development timelines and success rate for MCMs. FDA will also expand technical assistance to developers for the highest priority MCMs.

2. Why is this funding necessary?

The FDA plays a vital role in protecting the United States from chemical, biological, radiological, and nuclear (CBRN) threats, and from emerging infectious diseases. FDA is responsible for ensuring that MCMs – such as drugs, vaccines, and diagnostic tests – to counter these threats are safe, effective, and secure. In addition, FDA works closely with Federal partners through the Department of Health and Human Services' (HHS) Public Health Emergency Medical Countermeasures Enterprise (Enterprise) to build and sustain the MCM programs necessary to respond to public health emergencies.

The Threat: According to the U.S. intelligence community, CBRN weapons and emerging infectious diseases present real, substantial and growing threats to the national security of the United States, and will continue to do so for the foreseeable future. For example, the March 2011 unclassified annual threat assessment from the U.S. intelligence community states that:

> . . . many of the countries pursuing [weapons of mass destruction] programs will continue to try to improve their capabilities and level of self-sufficiency over the next decade. Nuclear, chemical, and/or biological weapons – or the production technologies and materials necessary to produce them – also may be acquired by states that do not now have such programs. Terrorist or insurgent organizations acting alone or through middlemen may acquire nuclear, chemical, and/or biological weapons and may seek opportunistic networks as service providers.[1]

The March 2011 threat assessment echoes a 2009 assessment. According to the U.S. intelligence community, "[o]ver the coming years, [the United States] will continue to face a substantial threat, including in the U.S. Homeland, from terrorists attempting to acquire biological, chemical, and possibly nuclear weapons and use them to conduct large-scale attacks."[2] This assessment also stressed that "[i]n particular . . . the terrorist use of biological agents represents a growing threat . . ."

In October 2011, the Honorable Tara O'Toole, Under Secretary for Science and Technology, U.S. Department of Homeland Security in testimony before the Committee on Homeland Security and Governmental Affairs described the growing biological weapons threat:

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[1] Clapper, J.R. Statement for the Record on the Worldwide Threat Assessment of the U.S. Intelligence Community for the Senate Armed Services Committee. *Annual Hearing to Receive Testimony on the Current and Future Worldwide Threats to the National Security of the United States*, Hearing, March 10, 2011. Available at: http://www.dni.gov/files/documents/Newsroom/Testimonies/20110310_testimony_clapper.pdf. Accessed February 15, 2013.

[2] Blair, D. Testimony before the Armed Services Committee, United States Senate. *Annual Threat Assessment of the Intelligence Community*, Hearing, March 10, 2009. Available at: http://www.dni.gov/files/documents/Newsroom/Testimonies/20090310_testimony.pdf. Accessed February 15, 2013.

> We are living in the midst of a biotechnology revolution where the knowledge and tools needed to acquire and disseminate a biological weapon are increasingly accessible. It is possible today to manipulate pathogens' characteristics (e.g. virulence, antibiotic resistance), and even to synthesize viruses from scratch. These procedures will inexorably become simpler and more available across the globe as technology continues to mature . . .Even small-scale attacks could be highly lethal and disruptive, and as has been noted, there is a real possibility of a campaign of bioattacks on multiple targets (the "reload" phenomenon) – because these weapons are self-replicating organisms. Moreover, it is not necessary for a nation-state to maintain a large stockpile of bioweapons to pose a significant asymmetric threat as the development of a significant offensive bioattack capability could occur within weeks or months.[3]

Numerous U.S. governmental reports have highlighted similar concerns.[4] For example, the *National Security Strategy* of 2010 notes that "[t]he effective dissemination of a lethal biological agent within a population center would endanger the lives of hundreds of thousands of people and have unprecedented economic, social, and political consequences."[5]

And in a November 2009 report, the National Security Council estimated that the economic cost of a well-executed bioterrorist attack on American soil could exceed one trillion dollars. Such an attack could have profound consequences for our way of life, for trust in government, and for our society and political order. [6]

Naturally occurring emerging infectious diseases also pose a growing threat and could have similar consequences.[7] For example, in 2006 the Congressional Budget Office

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[3] O'Toole, TJ. Testimony before the Homeland Security and Governmental Affairs Committee, United States Senate. Ten Years after 9/11 and the Anthrax Attacks: Protecting against Biological Threats, Hearing, October 18. 2011. Available at http://www.hsgac.senate.gov/hearings/ten-years-after-9/11-and-the-anthrax-attacks-protecting-against-biological-threats. Accessed February 15, 2013.

[4] *U.S. Government Judgments on the Threat of Biological Weapons*. Baltimore, MD: Center for Biosecurity of UPMC. March 2011. Available at http://www.upmc-biosecurity.org/website/resources/publications/2010/pdf/2010-01-19-gov_judgments_BWthreat.pdf. Accessed February 15, 2013.

[5] *National Security Strategy*. Washington, DC: The White House. May 2010. Available at http://www.whitehouse.gov/sites/default/files/rss_viewer/national_security_strategy.pdf. Accessed February 15, 2013.

[6] *National Strategy for Countering Biological Threats*. Washington, DC: White House, National Security Council. November, 2009. Available at: http://www.whitehouse.gov/sites/default/files/National_Strategy_for_Countering_BioThreats.pdf. Accessed February 15, 2013.

[7] See for example *Strategic Implications of Global Health* (ICA 2008-10D) [Washington, DC: National Intelligence Council; December 2008. Available at: http://www.dni.gov/files/documents/Special%20Report_ICA%20Global%20Health%202008.pdf (accessed February 15, 2013)] which assessed that while numerous infectious and noninfectious health conditions can potentially impact U.S. strategic interests, "…for the foreseeable future [infectious diseases] will remain the top health-related threat to U.S. national security…" noting that the U.S. population "…will continue to be vulnerable to emerging infectious diseases – many of which will originate overseas (e.g., HIV/AIDS, West Nile, and dengue fever) – including a potential influenza pandemic or an outbreak of a "mystery" disease (e.g., SARS.)"

estimated that in the year following a severe influenza pandemic, U.S. gross domestic product could decline by 4.25 percent, a loss of approximately $645 billion to the U.S. economy in current dollars.[8]

The FDA MCMi: In August 2010, HHS Secretary Sebelius released the results of a year-long review of the Enterprise. This review assessed U.S. readiness to reduce the impact of a future public health emergency and improve the nation's capacity to respond quickly and effectively to CBRN and emerging infectious disease threats.[9] The *Enterprise Review* revealed that regulatory uncertainties associated with MCM development are among the most significant obstacles to successful MCM development.[10]

The *Enterprise Review* identified key steps that the Federal government must take to modernize the Enterprise. In particular, the report highlighted how critical FDA is to the success of the Enterprise. The report also called for greater investment in regulatory innovation and MCM regulatory science and for FDA to take an even more active role in fostering the development and facilitating the availability of MCMs.

In response, FDA immediately launched its MCMi to enhance FDA's regulatory processes, to foster clear regulatory pathways for MCMs and to facilitate the timely use of available MCMs. The MCMi is a comprehensive program to address key challenges in three areas:

- Enhancing the regulatory review process for the highest priority MCMs and related technologies
- Advancing regulatory science for MCM development
- Modernizing the regulatory and legal framework

The FY 2014 investment will contribute to sustaining the MCMi and to protecting the United States from potentially catastrophic CBRN and emerging infectious disease threats. The MCMi is essential to reduce the slow pace of development and reverse the high failure rates associated with MCM development. In addition, the MCMi is essential to helping transform the Enterprise so it can respond faster and more nimbly to "…any attack or threat, known or unknown..." as envisioned in the *Enterprise Review*.

[8] *A Potential Influenza Pandemic: Possible Macroeconomic Effects and Policy Issues.* Washington, DC, Congressional Budget Office. December 8, 2005; revised July 27, 2006. Available at: http://www.cbo.gov/ftpdocs/69xx/doc6946/12-08-BirdFlu.pdf. Accessed February 15, 2013.

[9] Sebelius, K., Speech before the American Medical Association Third National Congress on Health System Readiness. Washington, DC: US Department of Health and Human Services; December 1, 2009. http://www.hhs.gov/secretary/speeches/sp20091201.html. Accessed February 15, 2013.

[10] *The Public Health Emergency Medical Countermeasures Enterprise Review – Transforming the Enterprise to Meet Long-Range National Needs*. Washington, DC: US Department of Health and Human Services. August 2010. Available at: https://www.medicalcountermeasures.gov/media/1138/mcmreviewfinalcover-508.pdf. Accessed February 15, 2013.

3. What has this program accomplished?

Since the announcement of the FDA MCMi in August 2010, FDA and its drug, device and biologics programs have worked aggressively to ensure that the United States has access to high-priority MCMs to respond to CBRN and emerging infectious disease threats, such as pandemic influenza.

MCMi Accomplishments: During its first two years, FDA made substantial progress to implement the MCMi using the one-time funding that HHS transferred to FDA to commence MCMi activities as well as the $20,038,000 Congress appropriated in FY 2012 to provide a base of funding for the MCMi. The FY 2012 appropriation allows FDA to sustain 70 of its 77 MCMi FTE and supports an investment in MCM regulatory science. The *MCMi Year 1 Status Report* and *Year-2 Program Update* summarize FDA's achievements as of September 2012[11][12]. For example, FDA:

- Issued a 5-Year strategic plan for the MCMi[13]
- Established Public Health and Security Action Teams for multiplex *in vitro* diagnostic tests, therapies and diagnostics for acute radiation syndrome, warfighter trauma care, MCM surveillance, and to address pediatric, pregnancy, and special population issues
- Held numerous public workshops and advisory committee meetings to obtain public input and expert advice on scientific, technical, and policy matters related to MCMs. Examples include: radiation biodosimetry devices; MCMs for burn mass casualty incidents; MCMs for pediatrics; drugs to treat smallpox; and Raxibacumab, an MCM to treat anthrax
- Launched a rigorous MCM regulatory science program that identified more than 100 intramural research projects for funding
- Issued a broad agency announcement (BAA) to solicit proposals for the extramural MCM regulatory science program; to date, a proposal by Stanford University to map immune responses to biothreat agents in humans and animals has been funded under this BAA
- Established partnerships with the National Institutes of Health (NIH), the Defense Advanced Research Projects Agency (DARPA), and the National Interagency Confederation for Biological Research (NICBR) to expand FDA's scientific and technological collaborations with federal partners to support the development and

[11] *FDA's Medical Countermeasures Initiative Year-1 Status Report*. Washington, DC: US Food and Drug Administration. September 2011. Available at http://www.fda.gov/downloads/EmergencyPreparedness/MedicalCountermeasures/UCM270750.pdf. Accessed February 15, 2013.
[12] *FDA's Medical Countermeasures Initiative Year-2 Program Update*. Washington, DC: US Food and Drug Administration. September 2011. Available at http://www.fda.gov/downloads/EmergencyPreparedness/MedicalCountermeasures/UCM330285.pdf. Accessed February 15, 2013.
[13] *FDA' Medical Countermeasures Initiative Strategic Plan 2012 – 2016*. Washington, DC: US Food and Drug Administration. September 2011. Available at Available at http://www.fda.gov/downloads/EmergencyPreparedness/MedicalCountermeasures/UCM286201.pdf.Accessed February 15, 2013.

availability of MCMs; held the MCMi Regulatory Science Symposium to present regulatory science projects underway at FDA and with leaders and partners in the field

- Issued draft guidance entitled “Highly Multiplexed Microbiological/Medical Countermeasure *in vitro* Nucleic Acid Based Diagnostic Devices”
- Collaborated with the Defense Threat Reduction Agency (DTRA) and the National Center for Biotechnology Information (NCBI), to establish a publicly available reference database that will be critical to developers seeking to validate their candidate multiplex *in vitro* diagnostic tests
- Launched a program to qualify animal models as drug development tools
- Launched a collaboration with the University of Texas Medical Branch (UTMB), Galveston National Laboratory to identify and share best practices for ensuring data integrity and quality from studies conducted in a biosafety level 4 high-containment environment (BSL 4)
- Issued an umbrella Emergency Use Authorization (EUA) for doxycycline post-exposure prophylaxis to support pre- and post-event activities for mass distribution and dispensing efforts to address an anthrax event and an amendment to the EUA for doxycycline emergency kits for United States Postal Service employees who volunteer to support implementing the National Postal Model for emergency response
- Worked with State and local public health authorities and responders to support preparedness and response capabilities at the state and community levels
- Developed legislative proposals to enhance emergency preparedness and response that were submitted to Congress
- Launched the MCMi professional development program, which includes threat briefings by experts to ensure that FDA reviewers are fully aware of the threats – and therefore the risks – as they conduct risk-benefit analyses on MCM products
- Approved several MCMs including: Levofloxacin (Levaquin) for the treatment and prophylaxis of plague; a next-generation portable ventilator; Raxibacumab injection to treat inhalational anthrax and to prevent inhalational anthrax when alternative therapies are not available or not appropriate; and several influenza diagnostic tests. In addition, FDA expanded the approved use of the influenza antiviral medication, Tamiflu (oseltamivir), to treat children as young as 2 weeks old.

Current MCMi Activities

With current funding, FDA will conduct the following MCMi activities:

- Sustain Public Health and Action Teams for warfighter trauma care, acute radiation syndrome, MCM surveillance, pediatric, pregnancy, and special population issues, and in vitro diagnostics
- Provide technical assistance to the developers of the highest-priority MCMs (MCMs procured by the U.S. government) to foster effective product development and to support regulatory review

- Strengthen extramural MCM regulatory science partnerships with NIH and DoD, focusing on tools to assess efficacy, MCM product quality, and advanced diagnostics
- Conduct the 2nd Annual FDA MCMi Regulatory Science Symposium to communicate regulatory science accomplishments and promote scientific engagement
- Work with Enterprise partners to fill data needs associated with the development of pre-EUA packages for stockpiled MCMs
- Continue collaboration with the UTMB, Galveston National Laboratory to identify and share best practices for ensuring data integrity and quality from studies conducted in a BSL 4 high-containment environment
- Implement a program to qualify animal models as drug development tools
- Release an expanded and renamed draft guidance for the *2009 Draft Guidance for Industry Animal Models—Essential Elements to Address Efficacy Under the Animal Rule*
- Foster MCM development through agreements with Enterprise partners that facilitate MCM collaboration, communication, and information sharing
- Identify and communicate best review practices for interfacing with and supporting MCM sponsors
- Enhance rapid deployment and pre-event planning and positioning of MCMs.

4. What activities will FY 2014 funding support?

With this FY 2014 funding, FDA will support 7 FTE that are performing MCM activities. Currently, FDA supports the 7 FTE with the one-time funding allocated to FDA under Public Laws 111-8 and 111-117. The FY 2014 initiative will allow FDA to sustain its full, current MCMi operating level of 77 FTE and to conduct the following MCMi activities.

A. Medical Countermeasures (+$3,114,000)

FDA MCMi Objective 1 – Enhance the Review and Approval Processes for MCMs: +$1,081,000

FDA will foster the development and deployment of MCMs by strengthening its program of technical assistance – including the development of regulatory management plans – for the developers of the highest-priority MCMs. FDA will also ready MCMs for use under an EUA in advance of an emergency.

CDER	+	*$840,000 / (3 FTE non-add)*
CDRH	+	*$241,000 / (1 FTE non-add)*

FDA MCMi Objective 2 – Advance Regulatory Science for MCM Development and Evaluation: +$1,792,000

FDA will sustain its MCM regulatory science program, relying heavily on partnerships with industry, academia and U.S. government partners that enable FDA to harness cutting-edge science and apply innovative approaches to the regulatory process to improve MCM development timelines and success rates. In particular, FDA will focus investments in regulatory science on:

- Developing and qualifying tools to assess efficacy, such as animal and biomimetic models
- Developing methods to assess product quality and assays to support the release of MCMs
- Developing and assessing advanced diagnostic tests
- Developing novel manufacturing platforms.

CBER + $252,000 / (1 FTE non-add)
CDRH + $241,000 / (1 FTE non-add)
FDA HQ +$1,299,000 / 0 FTE

FDA MCMi Objective 3 – Modernize the Legal, Regulatory, and Policy Framework for Effective Public Health Response: +$241,000

FDA will continue to work collaboratively with HHS to examine the legal framework and the regulatory and policy approaches for MCM development and availability to ensure these adequately support emergency preparedness and response. These efforts include strengthening FDA's program to support rapid deployment and pre-event planning and positioning of MCMs.

CDRH + $241,000 / (1 FTE non-add)

B. Rent Activities for Advancing Medical Countermeasures Initiative (+$396,000 / 0 FTE*)*

The $396,000 increase in budget authority will enable FDA to pay rent activity costs for employees supported by the FY 2014 MCMi increase. Funding these rent activities will reduce the need to redirect resources from core, mission-critical public health activities to pay rent activity costs.

5. How does this initiative support important public health priorities?

The FDA MCMi supports important national security and public health priorities. Through the MCMi, FDA is helping to ensure that Americans have access to the medicines and vaccines they need to counter a deliberate CBRN attack or a naturally occurring epidemic.

The FY 2014 budget request for MCMi supports the need for "rapid and reliable development of medical countermeasures to respond to public health threats," as articulated in the National Security Strategy of 2010. FDA's MCMi will also protect American's health and foster resilience in response to emergencies.

The FY 2014 funding will also help implement FDA priorities articulated in the HHS *Enterprise Review*, released on August 19, 2010.[14] As recommended by the review, FDA will promote MCM development by:

- Supporting robust engagement with sponsors and government partners to facilitate the development of critical MCM products
- Establishing clear regulatory pathways for developing MCMs
- Advancing FDA MCM regulatory science to identify and resolve gaps that prevent successful MCM development and approval
- Modernizing the legal, regulatory, and policy framework to foster the application of advances in regulatory science to the regulatory review process and supporting preparedness for and response to CBRN threats and emerging infectious disease threats through the availability of MCMs.

6. *What are the risks of not proceeding with this initiative?*

Not approving the FY 2014 MCMi budget request poses genuine risks for the health of Americans and the security of the United States:

- The Nation's ability to respond to natural or deliberate infectious disease outbreaks and CBRN threats will remain limited.
- FDA will not be able to sustain the MCMi program at the level necessary to support the priorities in the *Enterprise Review*.
- The Federal government will not be able to fulfill its responsibility to protect the nation's health and keep Americans safe during public health emergencies.
- The United States will not be able to realize the return on the multibillion-dollar investments it has made in biodefense during the past decade.

7. What will FDA accomplish with the initiative?

Funding this initiative will support:

- A highly interactive review process for MCMs and related technologies
- A strong FDA workforce with enhanced expertise in CBRN issues
- Active FDA engagement and collaboration with Federal MCM partners

[14] *The Public Health Emergency Medical Countermeasures Enterprise Review – Transforming the Enterprise to Meet Long-Range National Needs*. Washington, DC: US Department of Health and Human Services. August 2010. Available at: https://www.medicalcountermeasures.gov/media/1138/mcmreviewfinalcover-508.pdf. Accessed February 15, 2013.

- Clear, well-defined and appropriate regulatory and scientific plans for HHS' highest priority MCMs
- An MCM regulatory science program to foster MCM development
- An improved legal framework and improved regulatory and policy approaches to MCM development and use
- Faster development and availability of MCMs
- A more resilient Nation that is better able to cope with the CBRN and infectious disease threats
- Job creation and economic development since every bioscience job creates 5.8 additional jobs
- Stronger national security.

***FY 2014 Medical Countermeasures Performance Table*:**

FDA is using FDA-TRACK, the agency-wide performance management system, to track, analyze, and report monthly and quarterly performance measures, progress and accomplishments for FDA's most important initiatives. These initiatives include ongoing efforts as well as new efforts as showcased in the following FY 2014 performance tables. Upon finalization and receipt of the FY 2014 request, FDA will develop performance measures and/or key project milestones for the funded initiatives. These measures, milestones, and progress can be found on the FDA-TRACK website - www.fda.gov/fdatrack .

The following table contains performance items associated with this initiative.

Performance Measures	FY 2012 Enacted Performance Level	FY 2014 Performance Level +/- FY 2012 Enacted	Most Recent Actual
Enhance development, evaluation, approval, and surveillance processes for high-priority MCMs and platform technologies;	• Increase technical assistance to the developers of the highest-priority MCMs (i.e., MCMs that have been procured by the US government) to foster effective development and support regulatory review	• Foster the development and deployment of MCMs by: (1) strengthening its program to provide technical assistance—including the development of regulatory management plans—to the developers of the highest-priority MCMs; and (2) readying MCMs for use under an EUA in advance of an emergency	NA
Support MCM development and evaluation by establishing regulatory science programs for MCM products based on extramural, collaborative research programs	• Strengthen extramural MCM regulatory science partnerships with NIH and DoD with a focus on tools to assess efficacy, MCM product quality, and advanced diagnostics	• Sustain MCM regulatory science program that relies heavily on partnerships with industry, academia and additional U.S. government partners with a focus on developing tools to assess efficacy, MCM product quality, advanced diagnostics, and novel manufacturing platforms	NA

Performance Measures	FY 2012 Enacted Performance Level	FY 2014 Performance Level +/- FY 2012 Enacted	Most Recent Actual
Modernize the legal, regulatory, and policy framework for efficient preparedness and response by assessing current laws and regulations and proposing changes that will facilitate an efficient response to public health emergencies	• Enhance rapid deployment and pre-event planning and positioning of MCMs	• Strengthen program to support rapid deployment and pre-event planning and positioning of MCMs	NA

Safety Inspections in China
Budget Authority: +$10,000,000 / 19 FTE

The following table displays the budget authority for the Safety Inspections in China Initiative.

Safety Inspections in China

(Dollars in Millions)

Program	FY 2012 Enacted	FY 2013 CR	FY 2014 Request	+/- FY 2012 Enacted
Budget Authority:				
FDA Headquarters	$0.000	$0.000	$10.000	$10.000
Total	**$0.000**	**$0.000**	**$10.000**	**$10.000**

1. Initiative Summary

This FDA initiative supports a prevention-focused program for import safety in China. With this FY 2014 initiative, FDA will increase its capacity to detect and address risks of foods, drugs and ingredients manufactured in China and to assure that these products do not result in harm to Americans. This initiative will enhance FDA's ability to ensure that Chinese manufacturers, processors, packers, and distributors institute measures to assure that foods, drugs and ingredients imported to the United States are safe and meet FDA standards.

2. Why is this funding necessary?

Global production of goods that FDA regulates increased dramatically over the course of the last decade. The U.S. imports more finished products, and manufacturers increasingly use imported materials and ingredients in their U.S. production facilities. This trend makes the distinction between domestic and imported products obsolete.

This trend is increasingly evident in trade with China. China is the source of a large and growing volume of imported foods, drugs and ingredients.

3. What has this program accomplished?

While this program represents a new initiative, it will build on previous work of FDA's China Office, which currently includes a small cadre of in-country inspectors. Founded in 2008, FDA's China Office has contributed significantly towards a three-fold increase in annual food and drug inspections in China over the last four years. In-country inspectors have also performed reviews of China's inspectional system for foods, trained Chinese regulatory authorities in key technical areas, and enlisted Chinese authorities to observe FDA inspections in China.

4. What activities will the funds support?

Drug Manufacturing Inspections in China
(+$4,725,000 / 9 FTE)

With the resources requested in this initiative, FDA will perform additional foreign inspections in China, focusing on facilities that produce drugs and drug ingredients that pose the greatest risks to patients in the United States. FDA will also conduct training with Chinese drug authorities to enhance their ability to regulate pharmaceutical products exported to the United States, and will do outreach and education activities with Chinese manufacturers on implementing measures to meet FDA requirements for safety and efficacy.

Food Manufacturing Inspections in China
(+$3,675,000 /7 FTE)

With the budget authority resources in this initiative, FDA will perform additional inspections in China, focusing on facilities that produce higher-risk foods and food ingredients for export to the United States. FDA will also conduct training with Chinese food authorities to enhance their ability to regulate food exported to the United States, and will do outreach and education activities for Chinese manufacturers on implementing measures to meet FDA requirements for food safety.

Risk Modeling and Risk Analysis
(+$1,000,000 /3 FTE)

FDA will also expand risk modeling and risk analysis to improve FDA's ability to target inspection resources to high-risk foods and manufacturing that originate in China.

Program Support
(+$600,000 / 0 FTE)

The program support resources will ensure that FDA import safety activities in China receive the support necessary to achieve their public health outcomes. Program support activities include finance and budgeting, human resource assistance, contracting, billing, legal counsel, communication, ethics, headquarters coordination and related support functions.

5. How does this initiative support important public health priorities?

Funding for the China Initiative will allow FDA to strengthen the supply chain for foods, drugs and ingredients manufactured in China. The result will be fewer import safety emergencies, less foodborne illness and earlier identification of safety problems associated with foods, drugs and ingredients manufactured in China.

6. What are the risks of not proceeding with this initiative?

Without this initiative, FDA will not have the resources to adequately identify and address risks associated with foods, drugs and ingredients imported from China. Not funding the initiative could result in preventable harm to U.S. consumers and patients.

7. What will FDA accomplish with the initiative?

FDA views the China Initiative as a unique opportunity to work with Chinese industry and our regulatory counterparts in China. Through this initiative, Chinese regulators will enhance their understanding of FDA requirements and strengthen their capacity to assure the safety of the food and drugs that their industries export to the United States. Through FDA/China engagement, we also promote science-based and data-driven approaches and regulatory decisions integration by Chinese regulatory authorities.

Performance Tables:

FDA is using FDA-TRACK, the agency's program performance management system, to track, analyze, and report performance measures, progress, and accomplishments for FDA's most important initiatives. FDA is implementing the initiatives showcased in the following FY 2014 performance tables using FDA-TRACK.

When FDA receives these resources, FDA will publish quarterly progress and accomplishments on performance under this initiative at: http://www.fda.gov/AboutFDA/Transparency/track/default.htm

The following table contains information about performance commitments associated with this initiative, including accomplishments expected during FY 2014 and proposed program outputs during FY 2016.

Performance Measures	FY 2012 Performance Level	FY 2014 Performance Level +/- FY 2013	Most Recent Actual
Foreign In-Country Human Drug Inspections	0	Hire and train 9 FTE in 2014. (+120 in-country inspections in FY 2016)	N/A
Foreign In-Country Food Safety Inspections	0	Hire and train 7 FTE in 2014. (+135 in-country inspections in FY 2016)	N/A

Transforming Food Safety
Budget Authority: +$43,410,000/59 FTE
User Fees: +252,269,000/548 FTE

The following table displays the budget authority and user fees for the Transforming Food Safety Initiative in the FY 2014 Congressional Budget Justification:

Transforming Food Safety

(Dollars in Millions)

Program	FY 2012 Enacted[1]	FY 2013 CR[2]	FY 2014 Request	+/- FY 2012
Budget Authority:				
Foods	**$858.315**	**$863.568**	**$882.817**	**$24.502**
Center	257.488	259.064	266.408	8.920
Field Activities	600.827	604.504	616.409	15.582
Animal Drugs and Feeds	**$107.989**	**$108.650**	**$112.892**	**$4.903**
Center	57.450	57.802	61.711	4.261
Field Activities	50.539	50.848	51.181	0.642
National Center for Toxicological Research	**$10.207**	**10.269**	**10.233**	**0.026**
FDA Headquarters	**$64.188**	**64.581**	**70.331**	**6.143**
Other Rent and Rent Related	**$30.175**	**30.360**	**36.503**	**6.328**
GSA Rental Payments	**$73.833**	**74.285**	**75.341**	**1.508**
Total, Budget Authority, Salaries and Expenses	**$1,144.707**	**$1,151.713**	**$1,188.117**	**$43.410**
Food Export Cerification User Fee	**$0.000**	**$1.267**	**$1.267**	**1.267**
Food Reinspection User Fee	**$14.700**	**$14.790**	**$15.367**	**0.667**
Food and Feed Recall User Fee	**$12.364**	**$12.440**	**$12.925**	**0.561**
International Courier User Fee	**$0.000**	**$0.000**	**$1.175**	**1.175**
Food Facility Registration and Inspection Fee	**$0.000**	**$0.000**	**$58.936**	**58.936**
Food Import Fee	**$0.000**	**$0.000**	**$165.690**	**165.690**
Cosmetics User Fee	**$0.000**	**$0.000**	**$19.074**	**19.074**
Food Contact Substance Notification User Fee	**$0.000**	**$0.000**	**$4.999**	**4.999**
Total, Program level	**$1,171.771**	**$1,180.210**	**$1,467.550**	**$295.779**

[1] Comparability Adjustments for the Food and Veterinary Medicine Program reorganization approved in FY 2012, that started in FY 2013: -42 FTE and -$7.746M in the Foods Program; -8 FTE and -$1.109M in the Animal Drugs and Feeds Program; +50 FTE and +$8.855M in FDA Headquarters.

[2]Spending authority has been adjusted pursuant to PL 112-175, Section 101(c) for the applicable user fee programs

1. Initiative Summary

The FDA Food Safety Modernization Act of 2011 (FSMA) provided FDA with a compelling and dynamic public health mandate. FSMA directs FDA to establish standards for modern food and feed safety practices for those who grow, process, transport, store, and sell food and feed. These standards will transform the U.S. food safety system into one focused on understanding and preventing food and feed safety problems before they occur so that the number of foodborne illnesses and deaths will be significantly reduce and fewer resources – government, industry, and medical – will have to be diverted to crises after they occur.

Supported by food safety investments enacted by Congress for FY 2011 and FY 2012, the resources in this FY 2014 initiative will allow FDA to continue to establish the 21st century food safety system envisioned by FSMA. FDA will use the resources in this initiative to continue building prevention-focused domestic and import food and feed safety systems that implement FSMA authorities and oversight tools. These investments will provide industry with consistent and transparent food and feed safety guidance to ensure the safety of America's food and feed supply. FDA proposes two new user fees to support this initiative, a Food Import User Fee and a Food Facility Registration and Inspection Fee

FDA also proposes new user fees to support the Cosmetic and Food Contact Substance Notification Programs.

2. Why is this funding necessary?

A. Food Safety Modernization

The mission of the FDA Foods and Veterinary Medicine (FVM) Program is to protect and promote the health of humans and animals by ensuring the safety and proper labeling of America's food supply, as well as the safety of animal feed, the safety and effectiveness of animal drugs, and the safety of cosmetics. The federal investment in the FVM program is modest compared to the economic value it can deliver: reduced costs to industry, government, and the health care system due to fewer cases of foodborne illness. Currently, 48 million foodborne illnesses occur each year, resulting in an estimated 128,000 hospitalizations and 3,000 deaths. The average cost per case of foodborne illness is estimated at $1,626 – more than $78 billion per year.

The nation's food safety challenges are diverse and complex. Congress recognized the unique food and feed safety challenges that FDA faces when it gave FDA a modern legislative mandate under FSMA. The resources in this FY 2014 initiative are essential to address these challenges.

FSMA directs FDA to:

- build a food and feed safety system based on the public health principle of comprehensive prevention
- enhance FDA's focus on risk-based prioritization to ensure that FDA allocates resources in the most efficient manner possible to protect public health
- create a new import oversight system that addresses growing imports of food and feed produced and manufactured overseas
- establish partnerships across the public and private sectors to leverage resources and minimize hazards from farm to table.

FDA recognizes the fiscal pressures inherent in the current budget climate. However, these federal budget constraints come at a time when the FVM Program must expand

implement the 21st century food safety system that FSMA mandates, as it continues to meet its core food and feed safety and nutrition responsibilities.

FSMA rules and guidances are important prevention-focused standards to establish a framework for food and feed safety accountability and guide industry. Successfully implementing a comprehensive, national, prevention-based system will be impossible without these standards and FSMA implementation will be seriously hindered if initial progress is delayed.. Success will also require improvements across the food and feed supply chain that are inconceivable without collaborative efforts by all stakeholders to develop widely understood, science-based practices and controls that these standards will advance. .

FSMA is designed to ensure that domestic and international industries achieve high rates of compliance with prevention-oriented food and feed safety standards. FSMA enables FDA to work proactively to prevent contamination and to respond rapidly to identify the source and contain the spread of contamination when it occurs – all while operating in a growing global network of supply meeting demand.

This initiative will be funded, in part, by two new user fees, a Food Import User Fee and a Food Facility Registration and Inspection Fee. The resources in this initiative are essential to the success of FSMA, and, thus the health of the American public and the nation's economy. This FY 2014 investment will allow FDA to strengthen its food and feed safety enforcement tools and processes to support the preventive strategy and timely response to food and feed safety incidents.

B. Cosmetics User Fee

Every day, Americans use a wide variety of cosmetic products, including skin moisturizers, perfumes, lipsticks, nail polishes, eye and face make-up, shampoos, hair straighteners, hair colors, mouthwashes, and deodorants. Consumers expect their cosmetics – and the individual ingredients in cosmetics – to be safe. FDA plays a critical role in ensuring that the nation's cosmetics are among the safest in the world.

FDA is proposing new legislative authority to require domestic and foreign cosmetic manufacturers to pay an annual registration fee to support FDA cosmetic safety and other FDA cosmetic responsibilities. The user fees will improve FDA's capacity to promote greater safety and understanding of cosmetic products.

During the past decade, Americans have also seen an explosion in the numbers and types of cosmetic products sold annually. From FY 2004 to FY 2010, the number of cosmetics imports has nearly doubled, growing from approximately 968,000 import lines in FY 2004 to more than 1.9 million import lines in FY 2010. In the face of this growth, FDA has inadequate, incomplete, and often outdated data on cosmetic products and ingredients.

The cosmetic industry is also undergoing rapid and significant change. Manufacturing has become more global, cosmetics technology has become increasingly sophisticated, and cosmetics ingredients have become more complex. For example, the use of nanotechnology in cosmetics can result in products with different chemical or physical properties, which may pose different safety challenges.

Based on these challenges, FDA recommends a new approach to strengthen the FDA Cosmetics Program, by relying on a user fee program to supplement appropriations. The goal of this user fee proposal is to achieve a stable, sustainable, long-term source of funding for the FDA Cosmetics Program and accomplish priority activities to meet public health and industry goals.

C. Food Contact Substance Notification User Fee

FDA has statutory responsibility for the safety of all food contact substances in the United States. The food packaging industry that develops food contact substances has annual sales of more than $60 billion. To ensure the safety of these products, the Food and Drug Administration Modernization Act (FDAMA) of 1997 established a premarket notification process for food contact substances, known as the Food Contact Notification (FCN) Program.

Food contact substances include components of food packaging and food processing equipment that come in contact with food. The FCN program, which has been operational since 2000, is the preferred process for obtaining authorized uses of food contact substances. Under the FCN Program, food contact substances may be marketed 120 days after submitting a notification to FDA, unless FDA raises an objection. As this process does not require rulemaking, it is simpler, more efficient, and requires fewer resources than the food additive petition process used for food additives that are not food contact substances.

Due to its greater efficiency and predictability, FDA and industry have hailed the FCN Program as a significant regulatory success and an example of sensible regulation. The FCN Program supports applications for innovative food contact substances that help mitigate microbial food contamination and provide consumers with more healthful and safe food choices.

However, Section 409(h)(5) of the FD&C Act specifies that the FCN Program can operate only if adequately funded. The requirement for adequate funding protects public health by ensuring that FDA has sufficient resources to prevent the marketing of unsafe food contact substances. Under Section 409(h)(5), FDA must make the determination about adequate funding each fiscal year.

The user fees proposed in this initiative will assure that the FCN Program operates more predictably by providing a stable, sustainable, long-term source of funding to supplement budget authority appropriations. The addition of user fees will add predictability for FDA

and the regulated industry, to the benefit of consumers. The proposed user fees investment in the FCN Program will better position FDA to fulfill its public health mission and will promote greater safety and understanding of products being used in contact with food.

3. What has this program accomplished?

This summary does not identify all actions by FDA, but highlights the most prominent food and feed safety activities:

Regulatory Action

In January 2013, FDA proposed two new food safety rules for food processing and produce safety aimed at preventing and reducing foodborne illness. The proposals were drafted following extensive outreach to industry, consumer communities, other government agencies, and the global community over the last two years. The first proposed rule would require makers of food to be sold in the U.S., whether produced at a foreign- or domestic-based facility, to have written plans that identify microbiological, chemical physical, or radiological hazards that are reasonably likely to occur; specify the steps that will be put in place to prevent or minimize the hazards; identify monitoring procedures; record monitoring results; and specify what actions will be taken to correct problems that arise. The second rule proposes enforceable science and risk-based standards for the growing, harvesting, packing, and holding of fruits and vegetables on farms. These standards focus on agricultural water, soil amendments of biological origin, animal intrusion, worker health and hygiene, and equipment, tools, buildings, and sanitation. These two proposed rules are the first two of the foundational rules in FSMA and part of an integrated reform effort that focuses on prevention and addresses the safety of foods produced domestically and imported.

In October 2012, FDA issued draft guidance on the Necessity of the Use of Food Categories in Food Facility Registrations and Updates to Food Categories, as provided by Section 102 of the FDA Food Safety Modernization Act (FSMA). FSMA requires both domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the U.S. to register with the FDA. Requiring the submission of food product category information as part of a facility's registration will help FDA to better protect the public by enabling quicker, more accurate, and more focused responses to an actual or potential bioterrorist incident or other food related emergency.

In April 2012, FDA issued draft guidance on the effects that manufacturing changes, including changes related to nanotechnology, have on the status and safety of new and existing food and color additives. Nanotechnology is an evolving technology that allows scientists to create, explore, and manipulate materials on a scale measured in nanometers – particles so small that they cannot be seen with a regular microscope. The technology has a broad range of potential applications, such as the packaging of food or altering the look and feel of cosmetics. The draft guidance is for manufacturers of food

ingredients and food contact substances (FCS), and the end users of food ingredients and FCS including food ingredients that are color additives. The guidance is intended to describe the factors industry should consider when determining how to implement a significant change in the manufacturing process when a food substance already in the market.

In March 2012, FDA issued guidance to address testing procedures for *Salmonella* species (spp.) in human foods and direct-human-contact animal foods, and the interpretation of test results, when the presence of *Salmonella* spp. in the food may render the food injurious to human health. The guidance states that facilities that manufacture, process, pack or hold human foods or direct-human-contact animal foods intended for distribution to consumers, institutions, or food processors should use valid methods when conducting testing for *Salmonella* spp.

In February 2012, FDA issued an interim final rule amending its regulations on record-keeping by food firms to be consistent with FDA's access to records, as expanded by FSMA. The expanded records-access authority is expected to improve FDA's ability to respond to and contain safety problems with the human food supply. FDA also published an update to its guidance for industry, "Questions and Answers Regarding Establishment and Maintenance of Records (Edition 4)," to ensure the guidance is consistent with the new FSMA requirements. The interim final rule allows FDA access to records beyond those relating to specific suspect food articles if the Agency reasonably believes that the other products are likely to be affected in a similar manner.

Establish Alliances

In July 2012, FDA developed criteria to identify high risk firms for priority inspections under the FSMA mandate. In addition, FDA initiated a collaborative project betweenthe Minneapolis District Office and states within the district to identify common elements for FDA and States when doing feed facility inspections.

In April 2012**,** the FDA Coordinated Outbreak Response and Evaluation Network (CORE) worked with the Veterinary-Laboratory Investigation and Response Network (Vet-LIRN) on the recent *Salmonella infantis* outbreak. Vet-LIRN integrates state and federal laboratories, resources, and expertise to achieve timely and accurate reporting, identification, and analyzing of chemical and microbiological contamination events related to animal feed. By partnering with Vet-LIRN, FDA was able to assist the Centers for Disease Control and Prevention (CDC) by testing pet samples from households with human patients using collaborative agreement laboratories that had recently harmonized testing methods for this pathogen in canine feces. In FY 2012, the total number of collaborating laboratories in Vet-LIRN rose from nine to 26.

Transparency and Information Sharing

In February 2012, FDA issued an Interim Final Rule and Guidance on FDA's Access to Records. In addition to the interim final rule, FDA also published a draft guidance and questions and answers for industry. FSMA expands FDA's former records access beyond records related to the specific suspect article of food that FDA reasonably believes is adulterated and presents a threat of serious adverse health consequences or death to humans or animals to now include records relating to any article of food that is reasonably likely to be affected in a similar manner.

Foreign Engagement

In November 2012, Vet-LIRN began to lead FDA's testing program to investigate the root cause of pet jerky treat-associated illness. The activities included a meeting in China with the Administration of Quality Supervision, Inspection and Quarantine for bilateral discussions and scientific collaborations on this issue.

In February 2012, FDA issued a Report to Congress on FDA Foreign Offices required by FSMA. The report describes FDA's progress in establishing its foreign offices – 13 to date – as well as their accomplishments and the challenges faced by FDA in the increasingly globalized marketplace it oversees.

4. What activities will the funds support?

The resources in this FY 2014 initiative will allow FDA to expand critical activities for implementing FSMA to transform our food and feed safety program, including ensuring the safety of the growing volume of imported food and feed. The FY 2014 activities described below build on budget increases received in the FY 2011 and FY 2012 appropriations. The following activities will be supported by the proposed Budget Authority and User Fees (including an Import Fee and a Facility Registration and Inspection Fee). The specific details regarding the allocation of a particular source of funding for any given activity will depend on the final statutory language of any user fee legislation, as well as our trade obligations with respect to the import fee.

The overall priorities for modernizing and transforming the FDA food and feed safety program in FY 2014 are:

- Developing and implementing preventive control standards
- Increasing the frequency and accuracy of domestic and foreign inspections
- Training of FDA, state, and other regulatory partners in new inspectional protocols required to ensure uniform compliance with preventive controls requirements
- Continuing to build the capacity of FDA state partners in order to leverage their programs and resources
- Implementing FDA's new FSMA import authorities to ensure the efficient entry of safe imported foods and feeds.

A. Transforming Food Safety

Standards-setting for Food and Feed Safety (+$26,687,000 / 21 FTE)

Foodborne illnesses and other food safety problems are largely preventable if the parties involved in today's global food chain implement appropriate preventive measures at each step of the process. Regulations and guidances are important prevention-focused tools provide the framework for industry accountability for meeting appropriate standards under FSMA. The more successful the food and feed system is at each stage – producing, processing, transporting, and preparing foods and feeds – the safer the U.S. food and feed supply will be.

FDA will develop risk-based standards and guidances for the safe production of food and feed. As part of this initiative, FDA will work closely with food and feed industry experts to gain the detailed knowledge of specific sectors and operations needed to develop the science-based regulations and guidances required under FSMA to support industry efforts to adopt preventive controls and produce safety standards. FDA will also engage in outreach and dialogue with the food and feed industry to ensure that FDA regulations and guidance are practical and effective to ensure food and feed safety. Additionally, FDA will provide training and outreach to federal, State, local, tribal, territorial regulatory partners, industry, and consumers on implementation of new FSMA standards.

This initiative will also enable FDA to develop and implement a preventive, risk-based system that fully addresses all aspects of producing, processing, transporting and storing of animal food and feed. FDA will develop standards to require the animal food and feed industry to take necessary steps in preventing, eliminating, or reducing to acceptable levels, potential risks to human and animal health, including steps to:

- Eliminate or control risks from animal food and feed hazards
- Establish regulatory limits for animal food and feed hazards
- Develop guidance and provide training and outreach to regulatory partners and industry.

To implement and enforce preventive controls in food and feed processing facilities, FDA will train more than 1,100 FDA inspection personnel. FDA will also establish a high quality content delivery program to train an additional 2,400 state, tribal, and territorial food safety partners. The training will include preventive control inspection and enforcement methods to ensure that inspection personnel are prepared to conduct sound, effective inspections under the new preventive controls framework.

CFSAN: Food Facility Registration and Inspection Fee $8,802,000/ 11 FTE
CVM: BA $2,587,000 / 7 FTE; Food Facility Registration and Inspection Fee $760,000 / 3 FTE
ORA: Food Facility Registration and Inspection Fee $14,538,000

Domestic Inspections (+$4,198,000 / 8 FTE)

FSMA recognizes that preventive control standards can only improve food and feed safety to the extent that producers and processors comply with the standards. Therefore, domestic inspection initiatives are essential for FDA to provide oversight, ensure compliance, and respond effectively when problems emerge. Inspections are essential to hold industry accountable to produce safe food and feed.

These resources for domestic inspections will allow FDA to modernize inspection approaches and compliance programs. FDA will improve food and feed safety enforcement tools and processes to support the prevention strategy mandated by FSMA. FDA will use risk information to identify high risk firms, prioritize firms for inspections, determine and increase the frequency of inspections. In addition, FDA will conduct microbiological surveillance in strains such as *Salmonella* and monitor high priority commodities such as imported seafood and animal feeds. These improvements are essential to achieve the greatest public health value from FDA inspection and compliance programs and to successfully manage any safety-related compliance problems uncovered as a result of FSMA's increased frequency of domestic inspections.
CFSAN: Food Facility Registration and Inspection Fee $3,812,000 / 6 FTE
CVM: Food Facility Registration and Inspection Fee $386,000 / 2 FTE

Import Safety (+$154,845,000 / 289 FTE)

U.S. markets are open to food and feed imports from countries with divergent food and feed safety standards and with varying levels of food and feed safety oversight. Approximately 15 to 20 percent of all foods consumed in the U.S. originate from foreign sources. For some higher risk commodities, the percentage is higher. For example, 80 percent of the seafood and 25 to 35 percent of the produce eaten by American consumers is imported. This investment will support comprehensive, prevention-focused import food and feed safety programs that will place greater responsibility on those in the food supply chain – food and feed manufacturers, processors, packers, distributors, transporters, and importers – to ensure that imported food and feed are as safe those produced domestically.

FDA will develop and implement a variety of approaches to ensure the safety of imported foods and feeds, including assessments of foreign food safety systems and capacity building for foreign industry and regulatory partners. FDA will use data generated by these activities to prioritize FDA food and feed safety monitoring activities and thereby enhance the safety of the U.S. food and feed supply. These resources will improve consumer protection by allowing FDA to make better informed decisions about the admissibility of imported food and feed products. FDA will also periodically audit these programs and program participants using fee resources.

Additionally, FDA will use the fees to establish a national call center that can provide timely responses to inquiries concerning the import process or the status of imports. The call center will help industry meet its obligations under FSMA, improve overall compliance with FSMA rules, and reduce time to solve problems that hinder entry of a food.

FDA will also increase port/border coverage with more staff and longer hours of operation, thus providing better screening and a more efficient entry admissibility process for safe products. Moreover, capital investments will be made to acquire additional space at various border locations to support this effort. This will result in safer food, increased efficiency, better industry/FDA communication, reduced time to resolve problems, and improved movement of trade.

FDA will also invest in IT that will enhance risk information and risk-based decision making for import personnel. These tools, systems, and infrastructure allow FDA to improve and expedite the identification of threats to the public health, and ultimately reduce the incidence of foodborne illness outbreaks. In addition, this investment will support the design, testing, and implementation of a fee collection system to administer the import user fee program.

Moreover, this investment will allow support the Foreign Supplier Verification Program and provide program oversight. This program requires importers to provide assurances that the food and feed imported to the U.S. are safe and meet regulatory requirements.

FDA will also provide outreach and education on FSMA import provisions, including outreach to the import community and other federal agencies involved in the import process.

FDA will implement a quality management system and quality control measures for the import review process at all locations and provide dedicated quality management measures to assess and assure the consistency of the import review process.

CFSAN: BA $943,000 / 4 FTE; Food Import User Fee +$8,583,000 / 8 FTE
CVM: Food Import User Fee $1,439,000 / 6 FTE
ORA: BA $9,525,000 / 18 FTE; Food Import User Fee $134,355,000 / 253 FTE

Integrated Food Safety System (+$20,673,000 / 41 FTE)

FDA will continue to develop and implement a credible integrated national food safety system built on:

- Uniform regulatory program standards
- Strong oversight of the food and feed supply
- Stable, sustainable, multi-year infrastructure investments in state, local, tribal, and territorial regulatory and public health partners.

These investments will provide more uniform coverage and safety oversight of the food and feed supply.

As part of establishing a national integrated food and feed safety system, FDA will provide funding to regulatory and public health partners in the form of state grants, contracts or cooperative agreements to improve, strengthen and standardize regulatory activities among all partners. These investments will result in more consistent and credible oversight, application, and enforcement of food and feed safety laws and regulations.

This investment will also increase the number of FDA staff members that maintain and oversee assessments and audits of state food and feed contracts. This includes assessments of states enrolled in the Manufactured Food Regulatory Program Standards (MFRPS) program and in the Animal Feed Regulatory Program Standards (AFRPS) program. Correspondingly, this investment supports enhancements to the training that FDA provides to the states.
FDA will also: perform 18-month assessments and begin conducting 36-month assessments of states enrolled in the MFRPS; begin conducting training visits with states enrolled in AFRPS; collaborate with key FDA stakeholders to provide feedback on assessments to be used to enhance training and development provided to the States by FDA; and administer training and education programs for State and local food safety officials related to animal feed regulatory standards.

FDA will develop food and feed safety certification programs for FDA inspectors, investigators, and analysts, and for FDA's regulatory partners. FDA will also provide field liaisons to assist the states with implementing the Manufactured Food Regulatory Program Standards. This investment will improve food and feed safety by facilitating communication and ensuring that all parties are performing to a national program standard. In addition, FDA will conduct audits of regulatory and public health partners to measure their performance against FDA food and feed safety program standards.

In addition, FDA will expand the current FDA proficiency testing program to better target food and feed safety and food defense concerns in support of the FSMA mandate for laboratory accreditation. FDA will also evaluate and implement new methods to detect microbiological and chemical contaminants in food and update Foods Program manuals that establish standards for validating analysis methods. FDA will develop and validate certification testing instruments and provide scientific coordinators to serve as resources to support the states as FDA moves to national standards for laboratories. State laboratory accreditation will support the development of the infrastructure to support state programs, which will advance the acceptance and mutual reliance on accredited laboratory data. Accrediting state laboratories will also allow FDA to integrate and use analysis conducted at the state level for microbiological, chemical and microanalytical testing. FDA will then be able to establish an integrated consortium of laboratory networks to rapidly identifying and removing contaminated products from the market.

These actions will build lab capacity for partner labs and food safety programs, which will allow FDA to coordinate the development and validation of analytical methods and improve surveillance of foodborne illness. In addition, FDA will modify existing surveillance infrastructure to provide a platform for ongoing high priority pathogen detection in the food supply, expand the number of states engaged in ongoing surveillance, and expand the number and types of commodities under surveillance based on burden of illnesses estimates and food consumption patterns in the United States.

CFSAN: Food Facility Registration and Inspection Fee $3,746,000 / 5 FTE
ORA: BA $3,850,000 / 15 FTE; Food Facility Registration and Inspection Fee $13,077,000 / 21 FTE

Foreign Inspections (+$1,418,000 / 4 FTE)

To ensure that imported products are as safe as those produced domestically, FDA will develop and implement a variety of approaches to imported food safety, including improved foreign inspections.

FDA will expand critical enforcement and compliance support for foreign food facility inspections. These activities include inspection planning, foreign firm notification to request permission to conduct inspections, inspection reports review, development of decision support systems, and management of follow-up compliance actions.

CFSAN: Food Facility Registration and Inspection Fee $1,418,000 / 4 FTE

Risk Analysis (+$9,203,000 / 5 FTE)

In order to better understand and prevent foodborne outbreaks, FDA will invest in new risk analysis and prioritization tools and innovative information technology. For example, FDA's recent Produce Safety Standards proposed rule estimates that contaminated produce contributes an estimated 3.1 million illnesses annually in the U.S. at a cost of approximately $1.8 billion.[15] Effective prevention strategies and new technologies are needed to reduce these risks to consumers. Investments in risk analysis will provide a systematic and transparent approach to identify, characterize, and evaluate food and feed safety risks throughout the food and feed supply system and to evaluate the potential impact of control measures or intervention strategies.

FDA will develop, update, and validate predictive risk assessment models to improve FDA's understanding of the complex interactions of pathogens, foods (such as produce), the environment, and human foodborne illnesses. These resources will allow FDA to rank and prioritize food and feed safety concerns associated with both domestic and imported food and feed and identify how to apply FDA resources to achieve the best

[15] [15] Batz, Michael et al. "Ranking the Risk: The 10 Pathogen-Food Combination with the Greatest Burden on Public Health." Retrieved from http://www.rwjf.org/files/research/72267report.pdf

possible public health outcomes. FDA will also adapt risk analysis tools for use by the public and industry to improve understanding and precision of risk evaluation of FDA-regulated commodities and associated hazards, including imported foods and feeds.

CFSAN: BA $3, 850,000 / 2 FTE; Food Facility Registration and Inspection Fee $2,859,000 / 1 FTE; Food Import Fee $2,964,000 / 1 FTE
CVM: Food Facility Registration and Inspection Fee $380,000 / 1 FTE

Science for Food Safety (+$8,891,000 / 6 FTE)

Scientific research and analysis provide the basis for developing appropriate standards in regulations and guidances. This investment will allow FDA to establish food and feed safety standards that are based on the latest scientific developments and that address hazards from farm to table.

With these resources, FDA will invest in science based tools and methods to improve detection of contaminants and adulterants, as well as improve rapid screening methods. FDA will develop innovative methods and tools to validate preventive controls and to better detect pathogens and chemical contamination in foods, such as *Salmonella*, *E. coli* O157, *Listeria monocytogenes*, Hepatitis A, viruses, and toxins. FDA will also focus on improved analytical methods and rapid screening tools to better monitor compliance with new FSMA standards. This research will allow FDA to inform food standard setting and improve the speed and effectiveness of outbreak and contamination response, domestic and foreign inspections, and the screening of imported food.

FDA will also develop next generation methods to detect high priority contaminants in animal feeds and feed components. FDA will:

- Evaluate and customize commercially available systems to detect illegal drug residues in animal feed and animal derived products for human consumption
- Develop metabolism studies to identify marker residues used to develop and validate analytical methods to detect residues in imported and domestic animal feed
- Expand the technical capacity of its laboratory surveillance networks to analyze animal feed commodities for contamination.

CFSAN: BA $3,000,000 / 2 FTE; Food Facility Registration and Inspection Fee $2,183,000 / 1 FTE; Food Import Fee $2,263,000 / 1 FTE
CVM: BA $595,000 / 2 FTE

Planning and Response (+$1,067,000 / 3 FTE)

FDA will work with government and industry partners to develop new traceback tools and new systems that unify information received from FDA regulatory partners and private sources. FDA will also enhance existing systems, such as the Field Accomplishments and Compliance Tracking System, as well as expand tools for surveillance and outbreak

detection. FDA will further expand tools and databases to collect information from post-response activities. This effort will allow FDA to identify trends and improve the effectiveness of future response and prevention activities.

In the area of feed safety, FDA will develop a network of shared state, federal, and other laboratory partners to investigate potential animal food and feed contamination events. FDA will also work with regulatory partners to close current gaps in the oversight of the animal food and feed industry. FDA will determine which laboratory accreditation options will best ensure that participating laboratories perform competent testing and provide consistent and meaningful data that will enable compliance with established FDA standards and make surveillance possible in partnership with the Veterinary Laboratory Investigation and Response Network (Vet-LIRN).

The user fees in this initiative will also support efforts to respond to high priority chemical and microbial animal food, feed, and drug contamination events that could signal concerns for the human food system. Current initiatives in this area include development of a database of feed toxicant events and an investigation of *Salmonella* in veterinary diagnostic samples.

CVM: BA $827,000 / 2 FTE
ORA: Food Facility Registration and Inspection Fee $240,000 / 1 FTE

B. Cosmetic Safety (+$16,660,000 / 60 FTE (All UF))[16]

FDA will conduct the following activities with the new user fee resources in this initiative:

issue standards to establish and maintain a Cosmetic Registration Program
acquire, analyze, and apply scientific data and information to set U.S. cosmetic standards
maintain a strong U.S. presence in international standard-setting efforts
provide education, outreach, and training to industry and consumers
refine inspection and sampling of imported products and apply risk-based approaches to post-market monitoring of domestic and imported products, inspection, and other enforcement activities.

CFSAN: UF $12,253,000 / 42 FTE
ORA: UF $4,407,000 / 18 FTE

[16] In addition to the amounts displayed here, additional amounts to support this activity are also displayed within the Program Support and Rent Activities sections of this document.

C. Food Contact Substances Notification User Fee (+$4,548,000 / 7 FTE (All UF))[17]

With the user fee resources in this initiative, FDA will:

support the efficient and timely review of food contact notifications
update standards in and provide guidance for industry
conduct education, outreach, and training
participate in international harmonization and standard setting for food contact substances.

CFSAN: UF $4,548,000 / 7 FTE

D. Program Support (+$20,847,000 / 56 FTE)

The FY 2014 Implementing the FSMA initiative includes resources to ensure that programs participating in this initiative receive the support necessary to achieve their public health outcomes. Program support includes activities such as:

finance and budgeting
human resources support
contracting, billing, and legal support
communications, ethics, headquarters coordination, and related support functions.

E. Rent Activities (+$18,486,000 / 0 FTE)

The FY 2014 Transforming Food Safety initiative includes resources to pay the cost of General Services Administration (GSA) Rent and the Other Rent and Rent-Related costs for the 500 new employees that FDA will hire under this initiative. Paying the cost of the rent activities for this initiative is essential to achieve the performance and the public health goals of this initiative.

The GSA Rent account includes funds for payments to the Department of Homeland Security (DHS) for guard services and the operation of security systems at FDA facilities. The Other Rent and Rent-Related account includes funds for commercial rent and other payments related to leased facilities that are not part of the GSA building inventory.

5. How does this initiative support important public health priorities?

The Transforming Food Safety initiative builds on the food safety activities approved by Congress in FDA's appropriations for FY 2011 and FY 2012. The FY 2014 resources are part of a continued, multi-year FDA effort to implement and enforce FSMA and key operational strategies laid out in the *Foods and Veterinary Medicine Program Strategic Plan*. Funding this initiative will allow FDA to achieve the Administration's vision of a

[17] In addition to the amounts displayed here, additional amounts to support this activity are also displayed within the Program Support and Rent Activities sections of this document.

strong, reliable food and feed safety system for American consumers that also sustains the economic health of all segments of America's food and feed industry. The FY 2014 Transforming Food Safety Initiative also implements the following HHS strategic priorities:

implementing a 21st century food safety system
protecting Americans' health and safety during emergencies.

The Cosmetic User Fee in this initiative will strengthen FDA efforts to protect public health by preventing harm to consumers, ensuring the safety of cosmetic products, and removing unsafe cosmetic products from the market. By increasing the information that FDA obtains from the cosmetic registration system that will serve as the basis for assessing this user fee, FDA will develop necessary standards and guidance for industry.

The Food Contact Substances User Fee supports Executive Branch and public health priorities for food safety. With these resources, FDA will:

protect consumers by allowing FDA to conduct pre-market reviews of food contact substances
increase the availability of safe food contact substances
prevent unsafe food contact substances from reaching the marketplace
apply the most modern regulatory science to the review of food contact substances.

6. What are the risks of not proceeding with this initiative?

Lack of funding will severely limit FDA's ability to implement FSMA and create a modern food and feed safety system that is prevention-oriented, science-and risk-based, and efficient.
Without these resources, FDA will not have sufficient capacity to:

- Reduce the number of foodborne illnesses and deaths
- Identify sources of risk in the food and feed safety systems
- Reduce the number of unsafe or potentially unsafe imported foods
- Strengthen oversight of imported food and feed
- Improve domestic and foreign industry compliance with food and feed safety standards
- Reduce the time required to detect and respond to outbreaks
- Enhance food safety integration between federal, state, local, tribal, territorial, and foreign public health partners.

Without the user fees to support the Cosmetics Program, FDA will continue to lack vital information necessary to maintain oversight of the domestic cosmetic industry and engage in leadership on international harmonization. Furthermore, without knowledge of the full range of cosmetic products and ingredients marketed in the U.S. and the

domestic and foreign facilities that are involved in providing cosmetics to American consumers, FDA does not have the full capability to protect American consumers from unsafe products.

Without the user fees to support FDA's food contact substances program in this initiative, FDA faces the risk of reverting to the less efficient and less predictable Food Additive Petition (FAP) process for regulating food contact substances. Such a change will cost U.S. consumers more on a product-by-product basis. This change will also have a significant negative impact on industry innovation, as premarket authorizations with FAPs require longer review timeframes, thus delaying the entry of new food contact substances into the market and delaying industry's recovery of research and development costs. Moreover, without better knowledge of the full range of food contact products being marketed in the U.S., including those from foreign firms, FDA is hampered in its ability to effectively protect American consumers from unsafe packaging products.

7. What will FDA accomplish with the initiative?

The Transforming Food Safety initiative will help to accomplish one of FDA's primary goals, reducing illnesses and deaths caused by foodborne pathogens. Implementing this initiative will allow FDA to develop and deploy an integrated prevention-focused food and feed safety system, consistent with the *Food and Veterinary Medicine Program Strategic Plan*. The initiative will leverage partnerships and resources with federal, state, local, tribal, and territorial regulatory partners and foreign governments to significantly improve the effectiveness and efficiency in preventing and responding to food and feed safety problems.

Accomplishing these objectives will greatly enhance domestic and global efforts to substantially reduce foodborne illnesses caused by contamination of the food and feed supply for years to come.

***Performance Tables*:**

FY 2014 Implementing the Food Safety Modernization Act

FDA is using FDA-TRACK, the agency's program performance management system, to track, analyze, and report performance measures, progress, and accomplishments for FDA's most important initiatives. FDA is implementing the initiatives showcased in the following FY 2014 performance tables using FDA-TRACK.

When FDA receives these resources, FDA will publish quarterly progress and accomplishments on performance under this initiative at:
http://www.fda.gov/AboutFDA/Transparency/track/default.htm

The following tables contain information about performance commitments associated with this initiative, including accomplishments expected during FY 2014 and proposed program outputs during FY 2014.

Performance Measures	FY 2012 Performance Level	FY 2014 Performance Level +/- FY 2012	Most Recent Actual
Conduct import verification inspections to provide assurances that the food and feed imported to the U.S. are safe and meet regulatory requirements	N/A	+20 FTE – hire and train in 2014 to begin implementation of the Foreign Supplier Verification Program (FSVP)	N/A
The number of self-assessments completed by participating countries to determine whether their level of food safety oversight is comparable to the level of food safety oversight of the FDA. (Outcome)	5	+8	6
Conduct and validate risk assessments, including collection of data, data analysis, and peer review to populate risk models and to inform decision-making	Initiate: • Development of 2 new risk models • Expansion of 2 existing risk models • 2 peer reviews of risk data	Complete: • Development of 2 new risk models • Expansion of 2 existing risk models • 2 peer reviews of risk data	N/A
Development of an integrated IT system; maintenance and evaluation of foods/feeds rules in PREDICT	• Develop approaches to integrate IT systems • Begin developing data rules to incorporate data from other data sources	• Initiate integration of IT systems • Begin targeting risk in PREDICT using other data sources as the data rules are completed	N/A
Build Confidence and Mutual Reliance on Peers through Comparability Assessments to Ensure the Implementation of the Food Safety and Modernization Act	• Design organizational structure of staff to oversee and conduct audits of domestic and international regulatory partners to measure performance against program standards • Continue work on and finalize rule making • Finalize guidance documents and procedures • Establish position descriptions	• Hire and train 15 FTEs including auditors and program managers • Implement internal procedures • Collaborate and communicate with key stakeholders on internal integration and operational stand up of the staff • Perform outreach with external stakeholders on final guidance documents and requirements	N/A
Enable Mutual Reliance on Peers in the Integrated Food Safety System	• Design organizational structure of branch to maintain and oversee assessments and audits of state food and feed contracts • Fully staff auditing	• Perform 18-month assessment and begin conducting 36-month assessment of states enrolled in the MFRPS. • Begin conducting training visits with states enrolled	FY11 actual: completed 2 18-month assessments FY12 Target:

Performance Measures	FY 2012 Performance Level	FY 2014 Performance Level +/- FY 2012	Most Recent Actual
	team/branch • Continue to perform 18-month assessment of states enrolled in the MFRPS • Initiate AFRPS contracts with states • Collaborate with key FDA stakeholders to provide feedback on assessments to be used to enhance training and development provided to the states by the Agency	in AFRPS • Collaborate with key FDA stakeholders to provide feedback on assessments to be used to enhance training and development provided to the states by the Agency	complete 9 18-month assessments
Draft guidance documents for animal food preventive controls regulations	N/A	Complete 1 draft guidance document	N/A
Develop and deliver training on the requirements under the animal food preventive controls regulations	N/A	Develop and deliver+1 training course	N/A
Conduct outreach with international public health agencies	N/A	Conduct 1 outreach activity	N/A
Monitor high priority food commodities	N/A	Issue 1 assignment in animal feeds	N/A
Ensure participating laboratories perform testing and provide consistent and meaningful data for FDA compliance and surveillance purposes	N/A	• Develop 1 white paper describing accreditation requirements • Conduct 2 microbial proficiency tests • Train12 laboratories to use a commercial system to detect illegal drug residues and conduct 1 proficiency test	N/A
Expand the technical capacity of laboratory surveillance networks to analyze animal feed commodities for contaminants	N/A	• +1 project developing next generation methods for high priority contaminants n animal feeds and feed components • Develop and evaluate commercially available systems for detection of illegal drug residues • Identify marker residues in imported and domestic animal feed products	N/A

FDA White Oak Consolidation
Budget Authority: +$17,658,000 / 0 FTE
User Fees: +283,000 / 0 FTE

The following table displays the budget authority and user fees for the White Oak Consolidation Initiative in the FY 2014 Congressional Justification.

FDA White Oak Consolidation
(dollars in thousands)

	FY 2012 Enacted	FY 2013 CR	FY 2014 Request	FY 2014 +/- FY 2012 Enacted
Program Level FDA White Oak Consolidation	**$43,981**	**$44,302**	**$61,922**	**$17,941**
Budget Authority FDA White Oak Consolidation	$40,386	$40,633	$58,044	$17,658
User Fees FDA White Oak Consolidation	$3,595	$3,669	$3,878	$283

Spending authority has been adjusted pursuant to PL 112-175, Section 101(c) for the applicable user fee programs.

1. Initiative Summary

The Food and Drug Administration (FDA) is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health. In light of these responsibilities, Congress has charged FDA to partner with General Services Administration (GSA) to establish state-of-the-art research facilities to ensure FDA's regulatory decisions are based on the best science possible.

2. Why is this funding necessary?

In accordance with the 2009 Master Plan for the White Oak Campus, the two largest laboratories – Buildings 52 and 72 – the Life Sciences-Biodefense Laboratory Complex (LSBC) and the expansion of the Vivarium will be completed in FY 2014. These facilities, along with two office buildings – Buildings 71 and 75 – in the Southeast Quadrant of the

Campus comprise almost 1.2 million square feet of specialized scientific and support facilities and office building to support research facilities. The requested funds for these new facilities will help ensure that FDA has the most appropriate technology available to test vaccines and other products in the approval pipeline that have the potential to protect Americans and creates stronger national security by allowing the nation to better cope with bioterrorism and infectious disease threats.

The LSBC is essential for FDA to facilitate development and licensure of new drugs, vaccines and immunoglobulins to prevent and treat illnesses due to exposure to bioterrorist pathogens – including anthrax, smallpox, tularemia, plague and hemorrhagic fevers. The close proximity of researchers in the laboratories and product reviewers in the offices integrates quality, safety, manufacturing and clinical review expertise, thereby enhancing the review process. Additionally, most of the work on new medical countermeasures requires access to Bio-safety Level-3 (BSL-3) containment, which will provide three times the current capacity allowing expansion of critical public health laboratory activities that support pandemic influenza preparedness and the medical countermeasure initiative. The BSL-3 labs include special containment equipment, autoclaves with bioseal double doors, special showers, and a clean room system.

The LSBC is also critical in national and global preparedness for pandemic and annual influenza surges and other emerging threats including, West Nile Virus, SARS, Dengue and Chagas' disease. This facility will allow FDA to improve the development of assays, standards and tests for products to prevent and treat these illnesses. The capability and capacity to evaluate influenza vaccines will be enhanced by the new LSBC. The new facility will support CBER's new redesignation as a World Health Organization (WHO) Collaborating Center for Biological Standardization and as reference National Regulatory Authority for eight prequalified vaccines, which include several influenza virus vaccines, rotavirus and pneumococcal vaccines.

The LSBC will also serve as a national resource for advancing microbiologic safety of blood and other biologic products and related science to improve product quality and prevent infectious disease contamination and transmission and enhance FDA's ability to test and evaluate blood and plasma products to help assure blood supply safety.

The Laboratories will allow FDA to better evaluate gene and cell therapy safety and effectiveness and facilitate more rapid approval of products such as cell-based cancer vaccines and stem cell therapies. FDA's ability to provide state-of-the-art science facilities is critical to public health and the vitality of US and global industry.

These high technology laboratories are being outfitted with the highest level of flexibility as requirements continue to change to keep pace with today's threats. Additional infrastructure is being provided in these laboratories to support the specialized design of the equipment and for emerging science and technology initiatives such as

nanotechnology, imaging, and flow cytometry. The LSBC has also been designed with extensive additional structural reinforcement of the floor area for three Nuclear Magnetic Resonance machines, including two to be moved and a new one to be added in the future.

Additionally, the LSBC will include an expanded Vivarium that will feature Non-Human Primate surgery suites, and MRI, special biosafety cabinets and stainless steel stations for procedures, and a pH waste neutralization system, with special piping, will be included to support these facilities.

3. What activities will the funds support?

The funds are needed to support the outfitting and required certification and operation of the two largest laboratories – Buildings 52 and 72, the LSBC, and the expansion of the Vivarium. This covers the installation, testing, commissioning, and functioning of the specialized equipment to including:

- Building automation operation and monitoring
- HEPA filter tests
- Air sensors
- Primary bio-containment device effectiveness
- Room pressurization control and power tests.

These funds are needed to allow FDA to properly equip, certify and operate the LSBC. FDA must make this investment in early FY 2014 to ensure that the laboratory is operational and ready for occupancy in the early Spring of 2014.

FDA will also use these funds to complete critical security features including: the expansion of the Central Utility Plant and additional infrastructure to support the laboratories and office complex. These funds are also needed for Campus operations and logistics programs including those to support the LSBC such as the maintenance of specialized equipment (BSL-3 containment equipment and Nuclear Magnetic Resonance and Magnetic Resonance Imaging machines). Expanded support services needed are needed to support the several thousand additional Campus employees moving in 2014. FDA will also use these funds to establish and maintain a critically-needed Safety Program to support operations in the LSBC, including the new BSL-3 labs.

4. How does this initiative support important public health priorities?

The LSBC is a key component for fulfilling FDA's regulatory mission by providing a means for FDA scientists to conduct research to support medical product innovation. This initiative will result in better, safer, more effective products for patients and enhance the science necessary to develop innovative products, allowing them to potentially reach the market faster. The LSBC will enable FDA's ability to regulate emerging technologies and increase preparedness in the event of an outbreak or bioterrorism threat.

5. What are the risks of not proceeding with this initiative?

Part of advancing regulatory science is investing in new technology to enable FDA to function as a 21st century regulatory agency. Determining the safety or efficacy of a drug, biologic, or device involves running tests or conducting experiments in a laboratory setting. These laboratories must be maintained and updated in a manner that is consistent with the work FDA entrusted to do. FDA cannot afford to lose ground in the technological revolution and must keep up or stay ahead in an effort to ensure the American public is able to consume and use the safest products, drugs, biologics, and devices possible.

- The ability to occupy and operate the new LSBC.is at risk. The lack of an operational laboratory will be a severe blow to critical CBER and CDER programs such as annual and pandemic influenza, medical countermeasures, blood, and other biological products, biosimilars, and regulatory science.
- FDA would not be able to establish and maintain a critically-needed Safety Program to support operations in the LSBC, including occupational medical and radiation safety management support.
- The generic drug program commitments negotiated for GDUFA will not be met.
- FDA will not keep pace with current technological and scientific advances adversely affecting the introduction of safe and effective medical products to the marketplace and reduced ability to keep pace with emerging threats.

Failure to proceed with this initiative will devastate the FDA's ability to carry out its public health mission and jeopardize the safety of its employees. GSA and FDA will have spent over $300 million in construction and related costs for buildings in the LSBC that would sit vacant since FDA will not be able to occupy and operate the LSBC..

Equally important, if critical CBER and CDER operations were to remain in their existing and outdated laboratory and office space, FDA will have to pay "double rent;" first for existing CBER/CDER space that FDA will be unable to vacate because of the unavailability of the LSBC, and second, for the nearly completed but unusable and unoccupied LSBC for which GSA Rental payments are required.

6. What will FDA accomplish with the initiative?

The American public - consumers and patients - will benefit with the advance of FDA's White Oak consolidation through the increased scientific and professional collaboration which will be achieved between the FDA offices and centers. Consolidation is a key strategy to meet the many challenges FDA faces resulting from changes in technology, markets, and consumer needs as it allows us the opportunity for innovation and more

effective use of technology and partnerships to meet these challenges. As the Campus expands, increased operational funding is needed to ensure that facilities and services to support this collaborative interaction are available.

FDA intends to ensure certification to allow occupancy of the new LSBC. The laboratories will be properly operated with the installation, testing, commissioning, and functioning of the specialized equipment.

FDA will be able to execute expanded Campus operations, logistics and support services - including those vital to support the LSCB such as specialized equipment maintenance. FDA will be able to establish and maintain a critically-needed Safety Program to support operations in the LSBC, including the new BSL-3 labs. FDA will also be able to complete critical security features including the expansion of the Central Utility Plant and the additional infrastructure needed for these new buildings.

FDA Current Law User Fees
+$500,135,000 / 1,248 FTE

1. Why is this funding necessary?

The current User Fee programs allow FDA to fulfill its mission of protecting the public health and accelerating innovation in the industry. The fees collected are used to support the review and surveillance of human and animal drugs, medical and mammography devices, food and feed, color additives, exports, and tobacco products.

Existing user fee laws authorize user fee increases for many of the FDA user fee programs. The authorized increases expand the available options for treating and curing diseases and addressing other important public health needs.

The following table displays funding for FY 2012 through FY 2014 for FDA current law user fees:

FDA Program Resource Table
(Dollars in Thousands)

Program	FY 2012 Enacted	FY 2012 Actual	FY 2013 [1] CR	FY 2014 Request	FY 2014 +/- FY 2012 Enacted
PDUFA	$702,172	$636,929	$718,669	$760,000	$57,828
Tobacco Control Act	$477,000	$295,711	$479,919	$534,000	$57,000
Generic Drug User Fee Amendments (GDUFA)	$0	$0	$299,000	$305,996	$305,996
MDUFA	$57,605	$70,328	$57,958	$114,833	$57,228
ADUFA [2]	$21,768	$16,137	$21,901	$23,600	$1,832
AGDUFA [2]	$5,706	$4,366	$5,741	$7,328	$1,622
Biosimilar User Fee Act (BsUFA)	$0	$0	$20,242	$20,716	$20,716
MQSA	$19,318	$14,527	$19,318	$19,318	$0
Food Reinspection	$14,700	$0	$14,790	$15,367	$667
Food and Feed Recall	$12,364	$0	$12,440	$12,925	$561
Color Certification	$7,843	$7,396	$7,843	$7,843	$0
Export Certification	$3,337	$4,214	$4,604	$4,604	$1,267
Priority Review Voucher (PRV) [3]	$4,582	$0	$0	$0	-$4,582
VQIP	$0	$0	$0	$0	$0
Total Current Law User Fees	**$1,326,395**	**$1,049,608**	**$1,662,425**	**$1,826,530**	**$500,135**

[1] Spending authority has been adjusted pursuant to PL 112-175, Section 101(c) for the applicable user fee programs.
[2] ADUFA and AGDUFA authorizations expire on October 1, 2013. Legislative proposals to reauthorize ADUFA and AGDUFA were transmitted to Congress in February 2013. The fee revenue levels in FY 2014 for ADUFA and AGDUFA are based on the legislative proposals.
[3] The program requires a sponsor to notify FDA of its intent to submit a PRV application 365 days prior to the submission. FDA has not yet received a notification for FY 2014; therefore, FDA does not anticipate receiving PRV fees in FY 2014.

2. What activities will the funds support?

PDUFA: +$57,828,000 / 72 FTE

The Prescription Drug User Fee Act (PDUFA) was enacted in 1992 and renewed in 1997 (PDUFA II), 2002 (PDUFA III), 2007 (PDUFA IV), and 2012 (PDUFA V) in the FDA Safety and Innovation Act (FDASIA). Under PDUFA V, fees paid by industry will support continued timely review of new prescription drugs, increase the use of standardized electronic data in product submissions, enhance communications with companies during drug development, and implement a structured benefit-risk framework in drug review.

PDUFA V also puts more focus on regulatory science, which seeks to create new tools, standards and approaches for use in assessing the safety, effectiveness, quality and performance of products. Among other things, user fees will advance the development of drugs for rare diseases and encourage the development of biomarkers.

The following table displays funding for FY 2012 through FY 2014 for PDUFA.

PDUFA Increase for FY 2014
(Dollars in Thousands)

Program	FY 2012 Enacted	FY 2012 Actual	FY 2013 CR	FY 2014 Request	+/- FY 2012 Enacted
CDER	$490,877	$470,444	$505,745	$534,526	$43,649
CBER	$101,010	$85,927	$104,071	$109,993	$8,983
Field Activities	$14,225	$8,265	$14,656	$15,489	$1,264
FDA Headquarters (HQ)	$42,541	$29,074	$43,829	$46,323	$3,782
White Oak Consolidation	$3,595	$3,415	$3,669	$3,878	$283
GSA Rent and Rent Related	$49,924	$39,804	$46,699	$49,791	-$133
Total	**$702,172**	**$636,929**	**$718,669**	**$760,000**	**$57,828**

Tobacco Act Program: +$57,000,000 / 266 FTE

The Family Smoking Prevention and Tobacco Control Act (the Act), was signed into law in 2009. The Act grants FDA important new authority to regulate manufacturing, marketing and distribution of tobacco products and authorizes FDA to collect user fees from manufacturers and importers of tobacco products to pay for new regulation activities.

The increase in tobacco user fees will allow FDA to continue to implement the Family Smoking and Prevention and Tobacco Control Act. Priority activities include:

- Preventing youth from using tobacco and helping Americans quit
- Promoting public understanding of the harmful constituents of tobacco products
- Developing the foundation of science for regulating tobacco
- Regulating tobacco products to reduce the toll of tobacco-related disease, disability and mortality.

The following table displays funding for FY 2012 through FY 2014 for the Tobacco Program:

Tobacco Act Program Increase for FY 2014
(Dollars in Thousands)

Program	FY 2012 Enacted	FY 2012 Actual	FY 2013 CR	FY 2014 Request	+/- FY 2012 Enacted
CTP	$448,501	$271,695	$451,246	$486,487	$37,986
Field Activities	$6,250	$5,441	$6,288	$14,989	$8,739
FDA Headquarters (HQ)	$15,196	$11,594	$15,289	$19,500	$4,304
GSA Rent and Rent Related	$7,053	$6,981	$7,096	$13,024	$5,971
Total	**$477,000**	**$295,711**	**$479,919**	**$534,000**	**$57,000**

GDUFA: + 305,996,000 / 690 FTE

The Generic Drug User Fee Amendments of 2012 (GDUFA) provides user fees for FDA to ensure timely review of applications for human generic drugs. The law requires industry to pay user fees to supplement the costs of reviewing human generic drug applications and inspecting facilities. Additional resources will enable the Agency to reduce a current backlog of pending applications, cut the average time required to review generic drug applications for safety, and increase risk-based inspections.

GDUFA is designed to build on the success of PDUFA. Over the past 20 years, PDUFA has ensured a more predictable, consistent, and streamlined premarket program for industry and helped speed access to new, safe and effective prescription drugs for patients. GDUFA will also enhance global supply chain safety by requiring that generic drug facilities and sites around the world self-identify.

The following table displays funding for FY 2012 through FY 2014 GDUFA:

GDUFA Increase for FY 2014
(Dollars in Thousands)

Program	FY 2012 Enacted	FY 2012 Actual	FY 2013 CR	FY 2014 Request	+/- FY 2012 Enacted
CDER	$0	$0	$202,731	$207,475	$207,475
CBER	$0	$0	$0	$774	$774
Field Activities	$0	$0	$51,811	$53,023	$53,023
FDA Headquarters (HQ)	$0	$0	$24,196	$23,988	$23,988
GSA Rent and Rent Related	$0	$0	$20,262	$20,736	$20,736
Total	**$0**	**$0**	**$299,000**	**$305,996**	**$305,996**

MDUFA: +$57,228,000 / 33 FTE

The Medical Device User Fee Act (MDUFA) authorizes FDA to collect user fees to supplement appropriations for the medical device review program. FDA collects fees from device manufacturers who submit premarket applications and premarket notifications and annual registration fees from certain device establishments.

The FDA Safety and Innovation Act (FDASIA), which Congress passed in 2012, reauthorized the user fee program for medical devices for the third time. The MDUFA III

agreement facilitates more timely access to safe and effective devices with the shared goal of reducing average total time to decisions and achieving greater transparency, consistency, predictability and productivity. This authority is in effect for five years.

The following table displays MDUFA funding for FY 2012 through FY 2014:

MDUFA Increase for FY 2014
(Dollars in Thousands)

Program	FY 2012 Enacted	FY 2012 Actual	FY 2013 CR	FY 2014 Request	+/- FY 2012 Enacted
CBER	$11,183	$8,231	$11,251	$10,301	($882)
CDRH	$33,177	$52,461	$33,380	$86,180	$53,003
Field Activities	$1,572	$2,028	$1,582	$2,105	$533
FDA Headquarters (HQ)	$5,975	$3,791	$6,012	$6,485	$510
GSA Rent and Rent Related	$5,698	$3,817	$5,733	$9,762	$4,064
Total	**$57,605**	**$70,328**	**$57,958**	**$114,833**	**$57,228**

ADUFA: +$1,832,000 / 5 FTE

In the Animal Drug User Fee Amendments of 2008 (ADUFA), Congress renewed FDA's authority to collect user fees for five years. ADUFA directs FDA to expedite the development of animal drugs and improve the quality and efficiency of animal drug review. ADUFA fees help ensure that FDA regulated animal drug products are safe and effective and are readily available for companion animals and animals intended for the food supply. ADUFA contributes to a cost-efficient, high quality animal drug review process that is predictable and performance driven.

The authority to collect ADUFA user fees expires on October 1, 2013. The requested increase for FY 2014 is based on the legislative proposal the Administration submitted to Congress in February 2013 to reauthorize ADUFA.

The following table displays ADUFA funding for FY 2012 through FY 2014:

ADUFA Increase for FY 2014
(Dollars in Thousands)

Program	FY 2012 Enacted	FY 2012 Actual	FY 2013 CR	*FY 2014 Legislative Proposal*	+/- FY 2012 Enacted
CVM	$19,261	$14,723	$19,379	*$20,768*	$1,507
Field Activities	$315	$141	$317	*$472*	$157
FDA Headquarters (HQ)	$873	$638	$878	*$944*	$71
GSA Rent and Rent Related	$1,319	$635	$1,327	*$1,416*	$97
Total	**$21,768**	**$16,137**	**$21,901**	***$23,600***	**$1,832**

AGDUFA: +$1,662,000 / 1 FTE

In the Animal Generic Drug User Fee Act of 2008 (AGDUFA), Congress provided FDA new authority to collect user fees to support the review of Abbreviated New Animal Drug Applications (ANADA) and related submissions. This authority, effective for five years,

directs FDA to expedite the development of generic animal drugs and improve the quality and efficiency of generic animal drug review.

Following the ADUFA model, AGDUFA provides funding to train and develop review staff. AGDUFA also provides funding to refine business processes and develop policies targeted to achieve more efficient review. The authority to collect AGDUFA user fees expires on October 1, 2013. The requested increase for FY 2014 is based on the legislative proposal the Administration submitted to Congress in February 2013 to reauthorize AGDUFA.

The following table displays AGDUFA funding for FY 2012 through FY 2014:

AGDUFA Increase for FY 2014
(Dollars in Thousands)

Program	FY 2012 Enacted	FY 2012 Actual	FY 2013 CR	*FY 2014 Legislative Proposal*	+/- FY 2012 Enacted
CVM	$4,898	$4,081	$4,928	*$6,302*	$1,404
Field Activities	$160	$0	$161	*$220*	$60
FDA Headquarters (HQ)	$228	$168	$230	*$293*	$65
GSA Rent and Rent Related	$420	$117	$422	*$513*	$93
Total	**$5,706**	**$4,366**	**$5,741**	***$7,328***	**$1,622**

BsUFA: +$20,716,000 / 72 FTE

The Biosimilar User Fee Act of 2012 (BsUFA), enacted as part of FDASIA, authorized FDA to receive user fees to support the review of marketing applications for biosimilar biological products. Biosimilar biological products are therapies produced by another manufacturer when the patent life of an innovator's biologic product expires.

Biological products include many life important therapies. These therapies include blockbuster products to treat a wide array of cancers. They also include therapies to treat anemia associated with certain cancers, renal dialysis and HIV. Biological products treat age-related macular degeneration and a wide range of rheumatologic diseases.

Biological products cost $15,000 to $150,000 or more per patient per year—prices that are far in excess of those charged for traditional drugs. These high prices represent a disproportionately high share of Federal government and private sector pharmaceutical costs. BsUFA provides FDA with resources to help review the biosimilar version of these products. Biosimilar biological products offer the potential for substantial savings.

The following table displays BsUFA funding for FY 2012 through FY 2014:

BsUFA Increase for FY 2014
(Dollars in Thousands)

Program	FY 2012 Enacted	FY 2012 Actual	FY 2013 CR	FY 2014 Request	+/- FY 2012 Enacted
CDER	$0	$0	$15,304	$15,676	$15,676
CBER	$0	$0	$774	$774	$774
Field Activities	$0	$0	$1,290	$1,322	$1,322
FDA Headquarters (HQ)	$0	$0	$1,290	$1,321	$1,321
GSA Rent and Rent Related	$0	$0	$1,584	$1,623	$1,623
Total	**$0**	**$0**	**$20,242**	**$20,716**	**$20,716**

MQSA: +$0 / +0 FTE

Breast cancer is the most commonly diagnosed cancer and the second leading cause of cancer deaths among American women. Experts estimate that one in eight women will contract breast cancer during their lifetime. The Mammography Quality Standards Act (MQSA), which Congress reauthorized in October 2004, addresses the public health need for safe and reliable mammography.

Congress enacted MQSA to ensure that all women have access to quality mammography to detect breast cancer in its earliest, most treatable stages. MQSA required that FDA certify mammography facilities and inspect facilities annually to ensure compliance with national quality and safety standards. The MQSA program supports FDA's strategic goal of reducing the risk of medical devices and radiation emitting products on the market by assuring product quality and correcting problems associated with their production and use.

MQSA directs FDA to assess, collect, and use fees to cover the costs of MQSA inspections, record keeping, and annual reports. In FY 2014, FDA estimates the same funding level as in FY 2012.

The following table displays MQSA funding for FY 2012 through FY 2014:

MQSA Increase for FY 2014
(Dollars in thousands)

Program	FY 2012 Enacted	FY 2012 Actual	FY 2013 CR	FY 2014 Request	+/- FY 2012 Enacted
CDRH	$6,003	$5,122	$6,003	$6,003	$0
Field Activities	$13,077	$9,135	$13,077	$13,077	$0
FDA Headquarters (HQ)	$238	$270	$238	$238	$0
Total	**$19,318**	**$14,527**	**$19,318**	**$19,318**	**$0**

Food Reinspection: +$667,000 / 73 FTE

FDA's Office of Regulatory Affairs (ORA) conducts postmarket inspections of foreign and domestic foods and animal feed facilities to assess their compliance with Good Manufacturing Practice requirements and other standards. Revenue from the Food and

Fees Reinspection User Fee will reimburse ORA and other FDA offices for costs associated with FTE and related expenses required to reinspect firms that fail to comply with FDA regulations designed to protect Americans from unsafe food and feed products.

The following table displays Food Reinspection funding for FY 2012 through FY 2014:

Food Reinspection Increase for FY 2014
(Dollars in Thousands)

Program	FY 2012 Enacted	FY 2012 Actual	FY 2013 CR	FY 2014 Request	+/- FY 2012 Enacted
Foods Field	$6,825	$0	$6,867	$7,134	$309
Animal Drugs & Feeds Field	$2,550	$0	$2,566	$2,666	$116
FDA Headquarters (HQ)	$3,395	$0	$3,416	$3,549	$154
GSA Rent and Rent Related	$1,930	$0	$1,941	$2,018	$88
Total	**$14,700**	**$0**	**$14,790**	**$15,367**	**$667**

Food and Feed Recall: +$561,000 / 31 FTE

Food and Feed Recall fees reimburse FDA for the cost of conducting a mandatory recall of an article of food or feed that is adulterated or misbranded. These mandatory recalls, also known as Class I recalls, involve circumstances when the use of, or exposure to, an article of food or feed will cause serious adverse health consequences or death to humans or animals.

The following table displays Food and Feed Recall Fee funding for FY 2012 through FY 2014:

Food and Feed Recall Increase for FY 2014
(Dollars in Thousands)

Program	FY 2012 Enacted	FY 2012 Actual	FY 2013 CR	FY 2014 Request	+/- FY 2012 Enacted
CFSAN	$464	$0	$467	$485	$21
Foods Field	$9,397	$0	$9,455	$9,823	$426
CVM	$521	$0	$524	$545	$24
Animal Drugs & Feeds Field	$639	$0	$643	$668	$29
FDA Headquarters (HQ)	$661	$0	$665	$691	$30
GSA Rent and Rent Related	$682	$0	$686	$713	$31
Total	**$12,364**	**$0**	**$12,440**	**$12,925**	**$561**

Color Certification: +$0 / 1 FTE

The Federal Food, Drug and Cosmetic Act (FFD&C) requires the certification of color additives. This program, which is administered by FDA's Center for Food Safety and Applied Nutrition, involves assessing the quality and safety of color additives used in foods, drugs, and cosmetics. The Color Certification Fees paid by firms contribute to the FDA Revolving Fund for Certification and Other Services, which pays the cost of salaries and expenses of employees who conduct color certifications.

The following table displays Color Certification funding for FY 2012 through FY 2014:

Color Certification Increase for FY 2014
(Dollars in Thousands)

Program	FY 2012 Enacted	FY 2012 Actual	FY 2013 CR	FY 2014 Request	+/- FY 2012 Enacted
	$7,843	$7,396	$7,843	$7,843	$0
Total	**$7,843**	**$7,396**	**$7,843**	**$7,843**	**$0**

Export Certification: +$1,267,000 / 4 FTE

FDA is required to issue certificates for the export of food, human drugs, animal drugs, animal feed, and devices. The certificates state that the product meets certain requirements of law. The purpose of the certificates is to promote the export of products made in the United States and to facilitate international trade. FDA's ability to issue certificates in a timely fashion depends on FDA securing the resources necessary to offset the costs associated with issuing export certificates.

The following table displays Export Certificate funding for FY 2012 through FY 2014:

Export Certification Increase for FY 2014
(Dollars in Thousands)

Program	FY 2012 Enacted	FY 2012 Actual	FY 2013 CR	FY 2014 Request	+/- FY 2012 Enacted
	$3,337	$4,214	$4,604	$4,604	$1,267
Total	**$3,337**	**$4,214**	**$4,604**	**$4,604**	**$1,267**

Voluntary Qualified Importer Program (VQIP): +$0 / 0 FTE

VQIP establishes a formalized voluntary program for importers to submit evidence attesting that the food complies with applicable food safety guidelines in return for expedited review of entries. VQIP will require manufacturing facilities to be certified and allows FDA to review specific manufacturer and product information.

FDA continues to develop VQIP as authorized by the Food Safety Modernization Act (FSMA). FDA must complete the design of the program and establish criteria that importers must meet to participate in VQIP. In addition, FDA is in the process of establishing guidance documents and updating all appropriate manuals and documents. FDA must also meet with industry and other Government agencies to brief them on VQIP and harmonize with existing initiatives like Custom and Border Protection's Customs Trade Partnership Against Terrorism (CTPAT) and Importers Self Assessment (ISA) programs.

Priority Review Voucher: -$4,582,000 / 0 FTE

The Food and Drug Administration Amendments Act of 2007 (FDAAA) established the priority review voucher program to encourage the development of treatments for tropical diseases. A priority review voucher (PRV) is issued to sponsors of approved applications

for products to treat certain tropical diseases. The voucher entitles the holder to priority review for a subsequent human drug or biological product application.
The user fee submitted when a PRV application is paid, is in addition to any other fee due under PDUFA. Submissions under the PRV user fee program have been infrequent to date. FDA received one submission and a fee of $4,582,000 in FY 2012. The program requires a sponsor to notify FDA of its intent to submit a PRV application 365 days prior to the submission. FDA has not yet received a notification for FY 2014. Therefore, FDA does not anticipate receiving PRV fees in FY 2014.

Priority Review Voucher User Fee Funding for FY 2014
(Dollars in Thousands)

Program	FY 2012 Enacted	FY 2012 Actual	FY 2013 CR	FY 2014 Request	+/- FY 2012 Enacted
	$4,582	$0	$0	$0	-$4,582
Total	**$4,582**	**$0**	**$0**	**$0**	**-$4,582**

3. How does this initiative support important public health priorities?

FDA user fee programs address a key priority of assuring the safety of essential food and medical products that benefit the health of Americans and the nation's animal population. User fee increases will also fund strategies to reduce the burden of illness and death caused by tobacco products.

4. What are the risks of not proceeding with this initiative?

If FDA does not receive the additional user fee resources authorized by law, then the loss of these fees will have the following consequences for the health of Americans and the U.S. animal population:

- FDA will fail to meet the performance commitments for faster medical device review (MDUFA), faster new and generic human drug review (PDUFA and GDUFA), new and generic animal drug review (ADUFA and AGDUFA), and biosimilar biological product review (BsUFA). The performance commitments are designed to ensure that FDA provides the public with earlier access to safe and effective medical products, thereby saving lives, relieving suffering, and improving the quality of life.
- FDA cannot increase the availability of experts to expand and improve consultation and outreach to industry and to reduce medical product development time.
- Rather than concentrate efforts on food and feed safety activities to prevent unsafe products from reaching the U.S. market, FDA will have to spend budget authority to remove harmful products from public distribution rather than impose these costs on the manufacturer or distributor (Recall User Fees).
- FDA will have to pay the cost of conducting reinspections of firms that fail to comply with safety standards for food and feed rather than concentrate its resources on other activities that support the health of the American public (Reinspection User Fees).

- FDA will have to divert resources to attest to the safety of medical products and food and feed products destined for export rather than having the exporter pay these costs (Export Certification Fees).
- FDA cannot adequately develop and implement effective public health strategies to reduce the burden of illness and death caused by tobacco products (Tobacco fees).
- FDA cannot adequately sustain patient access to safe and effective new products and cannot provide rapid, transparent, and predictable review of medical product applications.
- FDA cannot maximize safe and effective use of medical products by communicating benefits and risks more effectively.
- FDA cannot prevent harm from regulated products by improving problem detection and minimizing the time between detection and appropriate risk management response.

5. What will FDA accomplish with the initiative?

Providing the user fee increases authorized by statute will help FDA meet performance commitments in FY 2014 and future years. This initiative benefits more than 300 million Americans, plus countless international consumers who also benefit from U.S. leadership in medical product safety and security. This initiative also offers special benefits for American pet owners, farm and ranch operations, and other animal enterprises.

Increases for the recently authorized generic drug and biosimilar user fee programs provide funding to ensure that American consumers have timely access to safe, high-quality, and effective generic drugs, and the potential for enhanced access to and more choice in biological products.

FDA Proposed User Fees
+$269,434,000 / +518 FTE

FDA's proposed new user fee programs support food and medical product safety. The following table displays funding levels from FY 2012 Enacted through FY 2014 Request.

Proposed User Fee Funding
(Dollars in Thousands)

Proposed Programs	FY 2012 Enacted	FY 2012 Actual	FY 2013 CR	FY 2014 Request	+/- FY 2012 Enacted
Food Import	$0	$0	$0	$165,690	$165,690
Food Facility Registration and Inspection	$0	$0	$0	$58,936	$58,936
Cosmetics	$0	$0	$0	$19,074	$19,074
Medical Product Reinspection	$0	$0	$0	$15,043	$15,043
International Courier	$0	$0	$0	$5,692	$5,692
Food Contact Notification	$0	$0	$0	$4,999	$4,999
Total	**$0**	**$0**	**$0**	**$269,434**	**$269,434**

Food Import User Fee

FDA is proposing a new Food Import User Fee in FY 2014 to support FDA's food and feed safety efforts. The fee will have exemptions for small importers and a maximum charge for large importers. An important component of FDA's safety efforts is modernizing the import system, which has become more critical as the number of food and feed imports has been growing 10 percent per year. These imports pose a unique challenge to FDA since there are over 100,000 food and feed manufacturers in 130 countries exporting food and feed to the United States.

The new import fees target activities associated with the improvements to the import process. More specifically, these fees would both enhance the safety protections for imported food and feed while simultaneously improving the efficiency and speed of food and feed entry decisions by FDA inspectors, thus assisting the smooth flow of international trade in safe food and feed.

Food Facility Registration and Inspection User Fee

FDA is proposing a new Food Facility Registration and Inspection Fee in FY 2014 to support food and feed safety modernization activities. Revenue from registration fees will target new and improved activities required by the Food Safety Modernization Act (FSMA), to modernize FDA's inspection system. The fees will enable FDA to increase the

effectiveness of inspections through adoption of preventive controls, training of personnel to inspect against the new prevention standards, and developing new ways to educate and inform industry.

Fees will also support improvements in food and feed safety science and risk analysis, so that knowledge of the methods of food and feed contamination can contribute to preventing food and feed safety outbreaks, and ensure that resources are better focused on areas of greatest risk.

Cosmetics User Fee

FDA is proposing new legislative authority to require domestic and foreign cosmetic manufacturers to pay an annual registration fee to support FDA cosmetic safety and other FDA cosmetic responsibilities. The user fees will improve FDA's capacity to promote greater safety and understanding of cosmetic products.

During the past decade, Americans have seen an explosion in the numbers and types of cosmetic products sold annually. In the face of this growth, FDA has inadequate, incomplete, and often outdated data on cosmetic products and ingredients. The cosmetic industry is also undergoing rapid and significant change. Manufacturing has become more global, cosmetic technology has become increasingly sophisticated, and cosmetic ingredients have become more complex. For example, the use of nanotechnology in cosmetics may pose safety challenges.

FDA proposes to strengthen the FDA Cosmetics Program by relying on user fees to supplement appropriations of budget authority. With these resources, FDA will conduct priority Cosmetics Program activities that meet public health and industry goals.

Food Contact Substance Notification User Fee

FDA has statutory responsibility for the safety of all food contact substances in the United States. To ensure the safety of these products, the Food and Drug Administration Modernization Act of 1997 (FDAMA) established a premarket notification process for food contact substances, known as the Food Contact Notification (FCN) Program.

Section 409(h)(5) of the FD&C Act specifies that the FCN program can operate only if adequately funded. The requirement for adequate funding protects public health by ensuring that FDA has sufficient resources to prevent the marketing of unsafe food contact substances.

FDA is proposing this new user fee to assure that the FCN program operates more predictably by providing a stable, long-term source of funding to supplement budget authority appropriations.

International Courier User Fee

FDA is proposing a new International Courier User Fee to support activities associated with increased surveillance of FDA-regulated commodities, predominantly medical products, at express courier hubs. The user fee will address the growing volume of imports that enter through international couriers and the cost of FDA import operations to support international courier activities. Funding generated from this user fee program will allow FDA to conduct the following essential import safety activities:
conduct entry reviews
collect samples and conduct physical exams to determine whether a product can be admitted into the United States.
initiate compliance actions to prevent release of unsafe products
establish import controls to prevent future imports of unsafe products from reaching U.S. consumers.

Of the $5,692,000 requested in FY 2014, $1,175,000 supports Food Safety and $4,517,000 supports Medical Product Safety.

Medical Product Reinspection User Fees

FDA is proposing a new user fee to require establishments that FDA inspects to pay the full costs of reinspections and associated follow-up work. When FDA identifies violations during an inspection or issues a warning letter following an inspection, FDA conducts follow-up inspections to verify that the corrective action. FDA will impose the user fee when FDA reinspects facilities due to a failure to meet Good Manufacturing Practices (GMPs) or other important FDA requirements.

If facilities that fail to comply with FDA regulations do not bear the cost of reinspections, FDA must shift resources from other high-priority program activities to conduct reinspections.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
Appropriation Language

SALARIES AND EXPENSES

For necessary expenses of the Food and Drug Administration, including hire and purchase of passenger motor vehicles; for payment of space rental and related costs pursuant to Public Law 92–313 for programs and activities of the Food and Drug Administration which are included in this Act; for rental of special purpose space in the District of Columbia or elsewhere; for miscellaneous and emergency expenses of enforcement activities, authorized and approved by the Secretary and to be accounted for solely on the Secretary's certificate, not to exceed $25,000; and notwithstanding section 521 of Public Law 107–188; **[**$3,083,408,000:**]** *$3,957,738,000: Provided*, That, of the amount provided under this heading, **[**$30,530,000**]** *$760,000,000* shall be derived from **[**animal**]** *prescription* drug user fees authorized by **[**section 740 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j-12)**]** *21 U.S.C. 379h,* and shall be credited to this account and remain available until expended; **[**$7,595,000**]** *$114,833,000* shall be derived from **[**animal generic drug**]** *medical devices* user fees authorized by **[**section 741 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j-21)**]** *21 U.S.C. 379j*, and shall be credited to this account and shall remain available until expended; **[**$505,000,000**]** *$534,000,000* shall be derived from tobacco product user fees authorized by 21 U.S.C. 387s*,* and shall be credited to this account and remain available until expended **[**; $12,925,000 shall be derived from food and feed recall fees authorized by section 743 of the Federal Food, Drug, and Cosmetic Act (Public Law 75–717), as amended by the Food Safety Modernization Act (Public Law 111–353), and shall be

credited to this account and remain available until expended; $15,367,000 shall be derived from food reinspection fees authorized by section 743 of the Federal Food, Drug, and Cosmetic Act (Public Law 75–717), as amended by the Food Safety Modernization Act (Public Law 111–353), and shall be credited to this account and remain available until expended; and amounts derived from voluntary qualified importer program fees authorized by section 743 of the Federal Food, Drug, and Cosmetic Act (Public Law 75–717), as amended by the Food Safety Modernization Act (Public Law 111–353), and shall be credited to this account and remain available until expended**]**: *Provided further*, That, in addition and notwithstanding any other provision under this heading, amounts collected for **[**animal**]** *prescription drug* user fees and **[**animal generic drug**]** *medical device* user fees that exceed the respective fiscal year **[**2013**]** *2014* limitations are appropriated and shall be credited to this account and remain available until expended: *Provided further*, That fees derived from **[**animal drug and animal generic drug**]** *prescription drug, medical device, human generic drug, and biosimilar biological product* assessments for fiscal year **[**2013 received during fiscal year 2013**]** *2014,* including any such fees **[**assessed**]** *collected* prior to fiscal year **[**2013**]** *2014* but credited for fiscal year **[**2013**]** *2014,* shall be subject to the fiscal year **[**2013**]** *2014* limitations: *Provided further*, That the Secretary may, prior to the due date for such fees, accept payment **[**of animal drug user fees and animal generic drug user fees authorized for fiscal year 2014, and that amounts of such fees assessed for fiscal year 2014 for which the Secretary accepts payment in**]** *during* fiscal year **[**2013 shall not be included in amounts provided**]** *2014 of user fees specified* under this heading *and authorized for fiscal year 2015, and that amounts of such fiscal year 2015 fees for which the Secretary accepts payment during fiscal year 2014 shall not*

be included in amounts provided under this heading: *Provided further*, That not to exceed $25,000 of this amount shall be for official reception and representation expenses, not otherwise provided for, as determined by the Commissioner.

In addition, *human generic drug user fees authorized by 21 U.S.C. 379j-42, biosimilar biological product fees authorized by 21 U.S.C. 379j-52,* mammography user fees authorized by 42 U.S.C. 263b, export certification user fees authorized by 21 U.S.C. 381, **[**and**]** priority review user fees authorized by 21 U.S.C. 360n*,* **[**may**]** *and food and feed recall and reinspection fees authorized by 21 U.S.C. 379j-31 shall* be credited to this account, to remain available until expended.

BUILDINGS AND FACILITIES

For plans, construction, repair, improvement, extension, alteration, and purchase of fixed equipment or facilities of or used by the Food and Drug Administration, where not otherwise provided, **[**$5,320,000**]** *$8,788,000*, to remain available until expended.

SALARIES AND EXPENSES

In addition, contingent upon the enactment of authorizing legislation, the Secretary shall assess a fee with respect to animal drugs and animal generic drugs: Provided, That fees of $23,600,000 with respect to animal drugs shall be credited to this account and remain available until expended; and $7,328,000 with respect to animal generic drugs shall be credited to this account and remain available until expended: Provided further, That in addition and notwithstanding any other provision under this heading, amounts collected for such animal drug user fees and animal generic drug user fees that exceed the respective fiscal year 2014 limitations are appropriated and shall be

credited to this account and remain available until expended: Provided further, That fees derived from such animal drugs and animal generic drugs assessments for fiscal year 2014, including any such fees collected prior to fiscal year 2014 but credited for fiscal 2014, shall be subject to the fiscal year 2014 limitations: Provided further, That the Secretary may, prior to the due date for such animal drug and animal generic drug user fees, accept payment during fiscal year 2014 of such fees authorized for fiscal year 2015, and that amounts of such fiscal year 2015 fees for which the Secretary accepts payment during fiscal year 2014 shall not be included in amounts provided under this heading.

In addition, contingent upon the enactment of authorizing legislation, the Secretary shall assess user fees with respect to food facility registrations and inspections, food imports, food contact notification activities, reinspection of medical product facilities, cosmetic activities, and international express courier import activities, and such fees shall be credited to this account and remain available until expended.

Language Analysis

Language Provision	Explanation
Reinspection of Medical Product Facilities	The Administration will propose legislation to allow FDA to collect fees for reinspection of medical product facilities. The additional resources, estimated at $15,043,000 will enable FDA to reinspect medical product facilities which is vital for ensuring compliance with prior inspections.
Food Inspection and Facility Registration User Fee	The Administration will propose legislation to allow FDA to collect a fee for food establishment registration and inspection. The additional resources will generate an estimated $59,000,000 to support food safety modernization activities. Revenue would target new and improved activities required by FSMA, most significantly funding to modernize FDA's inspection system~~,~~ by increasing the effectiveness of inspection through adoption of preventive controls and by training of personnel to inspect against the new prevention standards as well as developing new ways of educating and informing industry.
International Courier User Fee	The Administration will propose legislation to allow FDA to collect fees for international couriers. The additional resources are estimated at $5,692,000.
Cosmetic User Fee	The Administration will propose legislation to allow FDA to collect fees for cosmetic safety. The additional resources, estimated at $19,074,000, will allow FDA to establish and maintain a Cosmetic Registration Program.
Food Contact Notification User Fee	The Administration will propose legislation to allow FDA to collect fees for food contact and notification. The additional resources, estimated at $4,999,000, will support FDA's efficient and timely review of food contact notifications.
Food Import Fee	The Administration will propose legislation to allow FDA to collect for food imports, which will generate an estimated $166,000,000 million to support FDA's food safety efforts. The fee will have exemptions for small importers and a maximum charge for large importers.

Language Provision	Explanation
Provided further, That fees derived from prescription drug, medical device, human generic drug, and biosimilar biological product assessments for fiscal year 2014, including any such fees collected prior to fiscal year 2014 but credited for fiscal year 2014, shall be subject to the fiscal year 2014 limitations	This language modifies a long standing provision included in past years.
Provided further, That the Secretary may, prior to the due date for such fees, accept payment during fiscal year 2014 of user fees specified under this heading and authorized for fiscal year 2015, and that amounts of such fiscal year 2015 fees for which the Secretary accepts payment during fiscal year 2014 shall not be included in amounts provided under this heading	This language modifies a provision that has been included in the past by clarifying language and by extending the provision to all fees under this heading. The provision a provides that FDA may collect in FY 2014 any advance payment for FY 2015 for the programs identified under the Salaries and Expenses paragraph.
In addition, human generic drug user fees authorized by 21 U.S.C. 379j-42, biosimilar biological product fees authorized by 21 U.S.C. 379j-52, mammography user fees authorized authorized by 42 U.S.C. 263b, export certification user fees authorized by U.S.C. 381, priority review user fees authorized by 21 U.S. C. 360n, and food and feed recall and reinspection fees authorized by 21 U.S.C. 379j-31 shall be credited to this account, to remain available until expended.	This provision provides indefinite appropriation language for human generic, biosimilar biological, and food and feed recall and reinspection fees, accordingly, language specifying dollar amounts for these programs is deleted.

Language Provision	Explanation
In addition, contingent upon the enactment of authorizing legislation, the Secretary shall assess a fee with respect to animal drugs and animal generic drugs: Provided, That fees of $23,600,000 with respect to animal drugs shall be credited to this account and remain available until expended; and $7,328,000 with respect to animal generic drugs shall be credited to this account and remain available until expended	This provision proposes language for reauthorization for ADUFA and AGDUFA. This provision allows FDA to collect animal drug and animal generic drug user fees. .
Provided further, That in addition and notwithstanding any other provision under this heading, amounts collected for such animal drug user fees and animal generic drug user fees that exceed the respective fiscal year 2014 limitations are appropriated and shall be credited to this account and remain available until expended:	This provision allows FDA to collect excess fees for animal drugs and animal generic drugs
In addition, contingent upon the enactment of authorizing legislation, the Secretary shall assess user fees with respect to food facility registrations and inspections, food imports, food contact notification activities, reinspection of medical product facilities, cosmetic activities, and international express courier import activities, and such fees shall be credited to this account and remain available until expended.	This provision allows collection of new user fees in support of food and medical product safety.

Budget Tables
Congressional Appropriations Table
(Dollars in Thousands)

PROGRAM	BUDGET AUTHORITY																	
	FY 2012		Changes from FY 2012												Total Budget Authority Changes		FY 2013 Budget Authority	
			Rent and Infrastructure		Pay Increase	Safety Inspections in China		Advancing Medical Countermeasures		Food Safety Modernization		Rent Absorption		Base Adjustment				
	FTE	$000	FTE	$000	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Foods	**3,642**	**858,315**	**0**	**0**	**3,764**	**0**	**0**	**0**	**0**	**40**	**20,738**	**0**	**0**	**0**	**0**	**40**	**24,502**	**3,682**	**882,817**
CFSAN	*897*	*257,488*			*1,127*					*8*	*7,793*	*0*		*0*	*0*	*8*	*8,920*	*905*	*266,408*
Field Activities	*2,745*	*600,827*			*2,637*					*32*	*12,945*	*0*		*0*	*0*	*32*	*15,582*	*2,777*	*616,409*
Human Drugs	**2,040**	**477,810**	**0**	**0**	**2,099**	**0**	**0**	**0**	**840**	**0**	**0**	**0**	**0**	**-21**	**-14,799**	**-21**	**-11,860**	**2,019**	**465,950**
CDER	*1,301*	*347,817*			*1,528*			*0*	*840*			*0*		*-2*	*-10,771*	*-2*	*-8,403*	*1,299*	*339,414*
Field Activities	*739*	*129,993*			*571*							*0*		*-19*	*-4,028*	*-19*	*-3,457*	*720*	*126,536*
Biologics	**905**	**212,224**	**0**	**0**	**932**	**0**	**0**	**0**	**252**	**0**	**0**	**0**	**0**	**-13**	**-2,649**	**-13**	**-1,465**	**892**	**210,759**
CBER	*672*	*171,711*			*755*			*0*	*252*					*-11*	*-2,143*	*-11*	*-1,136*	*661*	*170,575*
Field Activities	*233*	*40,513*			*177*							*0*		*-2*	*-506*	*-2*	*-329*	*231*	*40,184*
Animal Drugs & Feeds	**702**	**136,912**	**0**	**0**	**598**	**0**	**0**	**0**	**0**	**12**	**4,439**	**0**	**0**	**-2**	**-383**	**10**	**4,654**	**712**	**141,566**
CVM	*413*	*83,707*			*365*					*11*	*4,009*	*0*		*-1*	*-235*	*10*	*4,139*	*423*	*87,846*
Field Activities	*289*	*53,205*			*233*					*1*	*430*	*0*		*-1*	*-148*	*0*	*515*	*289*	*53,720*
Device & Radiological Products	**1,611**	**322,672**	**0**	**0**	**1,417**	**0**	**0**	**0**	**723**	**0**	**0**	**0**	**0**	**-29**	**-4,268**	**-29**	**-2,128**	**1,582**	**320,544**
CDRH	*1,139*	*241,475*			*1,060*			*0*	*723*					*-23*	*-3,194*	*-23*	*-1,411*	*1,116*	*240,064*
Field Activities	*472*	*81,197*			*357*							*0*		*-6*	*-1,074*	*-6*	*-717*	*466*	*80,480*
NCTR	**272**	**60,039**	**0**		**263**									**0**	**-808**	*0*	**-545**	**272**	**59,494**
Center for Tobacco Products	**0**	**0**	**0**	**0**		**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
CTP		*0*			**0**											**0**	**0**	**0**	**0**
Field Activities		*0*			**0**											**0**	**0**	**0**	**0**
Other Activities	**756**	**162,559**	**0**	**0**	**727.000**	**19**	**10,000**	**0**	**1,299**	**7**	**5,811**	**0**		**0**	**-7,285**	**26**	**10,552**	**782**	**173,111**
Office of Regulatory Affairs [Non-Add]	***4,478***	***905,735***	***0***	***0***	***3,975***	***0***	***0***	***0***	***0***	***33***	***13,375***	***0***	***0***	***-28***	***-5,756***	***5***	***11,594***	***4,483***	***917,329***
White Oak Consolidation		**40,386**		**17,658**	**0**		**0**		**0**	*0*						**0**	**17,658**	**0**	**58,044**
Other Rent & Rent-Related		**65,598**		**2,284**	**0**		**0**		**396**		**6,328**				**0**	**0**	**9,008**	**0**	**74,606**
GSA Rent		**160,506**		**0**	**0**		**0**		**0**		**1,508**				**0**	**0**	**1,508**	**0**	**162,014**
															0				
Salaries & Expenses Increases	**9,927**	**2,497,021**	**0**	**19,942**	**9,800**	**19**	**10,000**	**0**	**3,510**	**59**	**38,824**	**0**	**0**	**-65**	**-30,192**	**13**	**51,884**	**9,940**	**2,548,905**
Non-Field	*5,449*	*1,324,796*	*0*	*0*	*5,825*	*19*	*10,000*	*0*	*3,114*	*26*	*17,613*	*0*	*0*	*-37*	*-24,436*	*8*	*12,116*	*5,457*	*1,336,912*
Field	*4,478*	*905,735*	*0*	*0*	*3,975*	*0*	*0*	*0*	*0*	*33*	*13,375*	*0*	*0*	*-28*	*-5,756*	*5*	*11,594*	*4,483*	*917,329*
Rents		*266,490*		*19,942*	*0*		*0*		*396*		*7,836*		*0*		*0*	*0*	*28,174*		*294,664*
Buildings and Facilities		**8,788**		**0**	**0**											**0**	**0**	**0**	**8,788**
Total	**9,927**	**2,505,809**	**0**	**19,942**	**9,800**	**19**	**10,000**	**0**	**3,510**	**59**	**38,824**	**0**	**0**	**-65**	**-30,192**	**13**	**51,884**	**9,940**	**2,557,693**

Congressional Appropriations Table
(Dollars in Thousands)

CURRENT USER FEES																		PROPOSED USER FEES												PROGRAM LEVEL	
PDUFA		MDUFMA		Tobacco Product Fees		Voluntary Qualified Importer (VQIP) Fees[1]		Food Reinspection Fees		Food Recall Fees		Generic Drug User Fee (GDUFA)		Biosimilar User Fee (BsUFA)		ADUFA		AGDUFA		Medical Products Reinspection User Fee		International Courier User Fee		Food Facility Registration and Inspection Fee		Food Import User Fee		Cosmetics User Fee		Food Contact Substance Notification User Fee		FY 2013 TOTAL Program Level	
FTE	*$000*	*FTE*	*$000*	*FTE*	*$000*	*$000*		*FTE*	*$000*	*FTE*	*$000*	*FTE*	*$000*	*FTE*	*$000*	*FTE*	*$000*	*FTE*	*$000*	*FTE*	*$000*	*FTE*	*$000*	*FTE*	*$000*	*FTE*	*$000*	*FTE*	*$000*	*FTE*	*$000*
0	**0**	**0**	**0**	**0**	**0**		**0**	**48**	**7,134**	**25**	**10,308**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**3**	**735**	**48**	**49,657**	**237**	**134,745**	**60**	**16,660**	**7**	**4,548**	**4,110**	**1,106,604**
							0			*2*	*485*													*28*	*22,820*	*10*	*13,810*	*42*	*12,253*	*7*	*4,548*	*994*	*320,324*
							0	*48*	*7,134*	*23*	*9,823*											*3*	*735*	*20*	*26,837*	*227*	*120,935*	*18*	*4,407*	*0*	*0*	*3,116*	*786,280*
2,162	**545,434**	**0**	**0**	**0**	**0**		**0**	**0**	**0**	**0**	**0**	**617**	**260,498**	**64**	**16,998**	**0**	**0**	**0**	**0**	**18**	**2,804**	**2**	**491**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**4,882**	**1,292,175**
2,115	*534,526*											*444*	*207,475*	*59*	*15,676*																	*3,917*	*1,097,091*
47	*10,908*											*173*	*53,023*	*5*	*1,322*					*18*	*2,804*	*2*	*491*									*965*	*195,084*
414	**114,574**	**41**	**10,493**	**0**	**0**		**0**	**0**	**0**	**0**	**0**	**3**	**774**	**3**	**774**	**0**	**0**	**0**	**0**	**3**	**572**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1,356**	**337,946**
408	*109,993*	*40*	*10,301*									*3*	*774*	*3*	*774*																	*1,115*	*292,417*
6	*4,581*	*1*	*192*									*0*	*0*	*0*	*0*					*3*	*572*											*241*	*45,529*
0	**0**	**0**	**0**	**0**	**0**		**0**	**18**	**2,666**	**4**	**1,213**	**0**	**0**	**0**	**0**	**68**	**21,240**	**21**	**6,522**	**1**	**143**	**0**	**0**	**8**	**2,544**	**32**	**14,859**	**0**	**0**	**0**	**0**	**864**	**190,753**
								0	*0*	*2*	*545*					*67*	*20,768*	*20*	*6,302*					*6*	*1,526*	*6*	*1,439*					*524*	*118,426*
								18	*2,666*	*2*	*668*					*1*	*472*	*1*	*220*	*1*	*143*			*2*	*1,018*	*26*	*13,420*					*340*	*72,327*
0	**0**	**366**	**88,093**	**0**	**0**		**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**24**	**3,651**	**15**	**3,678**	**0**	**0**			**0**	**0**	**0**	**0**	**1,987**	**415,966**
		356	*86,180*																													*1,472*	*326,244*
		10	*1,913*																	*24*	*3,651*	*15*	*3,678*									*515*	*89,722*
																																272	***59,494***
				640	**501,476**		**0**	**0**	**0**	**0**	**0**																					**640**	**501,476**
				570	**486,487**																											*570*	*486,487*
				70	*14,989*																											*70*	*14,989*
202	**46,323**	**29**	**6,485**	**52**	**19,500**		**0**	**7**	**3,549**	**2**	**691**	**70**	**$23,988**	**5**	**1,321**	**4**	**944**	**1**	**293**	**10**	**6,293**	**1**	**295**	**13**	**4,486**	**32**	**9,278**	**3**	**1,000**	**1**	**272**	***1,214***	***297,829***
53	***15,489***	***11***	***2,105***	***70***	***14,989***		***0***	***66***	***9,800***	***25***	***10,491***	***173***	***53,023***	***5***	***1,322***	***1***	***472***	***1***	***220***	***46***	***7,170***	***20***	***4,904***	***22***	***27,855***	***253***	***134,355***	***18***	***4,407***	***0***	***0***	***5,247***	***1,203,931***
	3,878		**0**		**0**		**0**		**0**		**0**						**0**		**0**												**0**	**61,922**
	26,794		**3,546**		**3,050**		**0**		**619**		**259**		**6,598**		**590**		**236**		**73**		**486**		**180**		**811**		**2,478**		**514**		**65**	**0**	**120,905**
	22,997		**6,216**		**9,974**		**0**		**1,399**		**454**		**14,138**		**1,033**		**1,180**		**440**		**1,094**		**313**		**1,438**		**4,330**		**900**		**114**	**0**	**228,034**
2,778	**760,000**	**436**	**114,833**	**692**	**534,000**		**0**	**73**	**15,367**	**31**	**12,925**	**690**	**305,996**	**72**	**20,716**	**72**	**23,600**	**22**	**7,328**	**56**	**15,043**	**21**	**5,692**	**69**	**58,936**	**301**	**165,690**	**63**	**19,074**	**8**	**4,999**	**15,324**	**4,613,104**
2,725	*690,842*	*425*	*102,966*	*622*	*505,987*		*0*	*7*	*3,549*	*6*	*1,721*	*517*	*232,237*	*67*	*17,771*	*71*	*21,712*	*21*	*6,595*	*10*	*6,293*	*1*	*295*	*47*	*28,832*	*48*	*24,527*	*45*	*13,253*	*8*	*4,820*	*10,077*	*2,998,312*
53	*15,489*	*11*	*2,105*	*70*	*14,989*		*0*	*66*	*9,800*	*25*	*10,491*	*173*	*53,023*	*5*	*1,322*	*1*	*472*	*1*	*220*	*46*	*7,170*	*20*	*4,904*	*22*	*27,855*	*253*	*134,355*	*18*	*4,407*	*0*	*0*	*5,247*	*1,203,931*
0	*53,669*	*0*	*9,762*		*13,024*		*0*		*2,018*		*713*		*20,736*		*1,623*	*0*	*1,416*	*0*	*513*		*1,580*		*493*		*2,249*		*6,808*		*1,414*		*179*		*410,861*
																																0	**8,788**
2,778	**760,000**	**436**	**114,833**	**692**	**534,000**		**0**	**73**	**15,367**	**31**	**12,925**	**690**	**305,996**	**72**	**20,716**	**72**	**23,600**	**22**	**7,328**	**56**	**15,043**	**21**	**5,692**	**69**	**58,936**	**301**	**165,690**	**63**	**19,074**	**8**	**4,999**	**15,324**	**4,621,892**

NOTE: This table does not include resources for indefinite user fees for MQSA and export and color certification.

Food and Drug Administration
Amounts Available for Obligation

(Dollars in Thousands)

	FY 2012 Actual	FY 2013 CR 1/	FY 2014 Request
General Fund Discretionary Appropriation:			
Appropriation	**2,506,553**	**2,521,145**	**2,557,693**
Subtotal, adjusted appropriation.....	**2,506,553**	**2,521,145**	**2,557,693**
Subtotal, adjusted general fund discr. appropriation....	**2,506,553**	**2,521,145**	**2,557,693**
Transfer Lines.....	2,000	2,000	2,000
Subtotal, adjusted mandatory. appropriation.....	**2,000**	**2,000**	**2,000**
Offsetting collections from:			
Non-federal source:	1,049,608	1,662,425	2,095,964
Total obligations.....	**3,558,161**	**4,185,570**	**4,655,657**
Obligations less ARRA (if applicable).....	-	-	-

1/ Spending authority has been adjusted pursuant to PL 112-175, Section 101(c) for the applicable user fee programs.

Food and Drug Administration
Summary of Changes

Dollars in thousands				
	Budget Authority	**User Fees**	**Program Level**	**Program Level FTE[1]**
FY 2012 [1]	**$2,505,809**	**$1,326,395**	**$3,832,204**	**13,496**
FY 2014 Program Changes:				
Budget Authority				
Pay Increase	$9,800		$9,800	0
Rent and Infrastructure	$19,942		$19,942	0
Base Adjustments	($30,192)		($30,192)	-65
Food Safety Modernization	$38,824		38,824	59
Advancing Medical Countermeasures	$3,510		$3,510	0
China Inspections	$10,000		$10,000	19
Subtotal: Budget Authority Program Changes	**$51,884**		**$51,884**	**13**
Total Budget Authority Change from FY 2012 Enacted	**$51,884**		**$51,884**	**13**
FY 2014 User Fee Changes:				
Current Law User Fees:				
PDUFA		$57,828	$57,828	192
MDUFMA		$57,228	$57,228	165
ADUFA		$1,832	$1,832	0
AGDUFA		$1,622	$1,622	0
Tobacco		$57,000	$57,000	266
MQSA		$0	$0	5
Color Certification		$0	$0	0
Export Certification		$1,267	$1,267	7
Food Reinspection User Fee		$667	667	0
Priority Review Voucher User fee		-$4,582	-4,582	0
Voluntary Qualified Importer Program (VQIP) User Fee		$0	0	0
Recall User Fee		$561	561	0
Generic Drug User Fee (GDUFA)		$305,996	$305,996	690
Biosimilar User Fee		$20,716	$20,716	72
Total Current Law User Fees:		**$500,135**	**$500,135**	**1,397**
Proposed User Fees:				
Medical Products Reinspection User Fee		$15,043	$15,043	56
International Courier User Fee		$5,692	$5,692	21
Food Establishment Registration and Inspection Fee		$58,936	$58,936	69
Food Import User Fee		$165,690	$165,690	301
Cosmetics User Fee		$19,074	$19,074	63
Food Contact User Fee		$4,999	$4,999	8
Total Proposed User Fees:		**$269,434**	**$269,434**	**518**
Total User Fee Changes from FY 2012 Enacted		**$769,569**	**$769,569**	**1,915**
Net Program Level Change from FY 2012 Enacted	**$51,884**	**$769,569**	**$821,453**	**1,928**
Total FDA Request for FY 2014	**$2,557,693**	**$2,095,964**	**$4,653,657**	**15,424**

[1] FY 2012, FY 2013 and FY 2014 do not include an estimated 101 reimbursable, 1 CRADA, 42 PEPFAR, 12 IDDA FTE and the associated funds. In addition, The FTE level for FY 2012 assumes the Enacted level.

All Purpose Tables:

Food and Drug Administration
Budget Authority

(Dollars in Thousands)										
	FY 2012		FY 2012		FY 2013		FY 2014 Request			
									+/- FY 2012	
Program[1,2]	Enacted		Actual		CR		President's Budget		Actual	Enacted
	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Salaries and Expenses:						0.00612				
Foods 3/……..	**3,642**	**858,315**	**3,546**	**866,920**	**3,611**	**863,568**	**3,682**	**882,817**	**136**	**24,502**
Center	897	257,488	882	265,158	911	259,064	905	266,408	23	8,920
Field Activities	2,745	600,827	2,664	601,762	2,700	604,504	2,777	616,409	113	15,582
Human Drugs	**2,040**	**477,810**	**1,933**	**477,623**	**1,997**	**480,735**	**2,019**	**465,950**	**86**	**(11,860)**
Center	1,301	347,817	1,213	347,633	1,265	349,946	1,299	339,414	86	(8,403)
Field Activities	739	129,993	720	129,990	732	130,789	720	126,536	-	(3,457)
Biologics	**905**	**212,224**	**876**	**212,298**	**896**	**213,523**	**892**	**210,759**	**16**	**(1,465)**
Center	672	171,711	652	171,788	668	172,762	661	170,575	9	(1,136)
Field Activities	233	40,513	224	40,510	228	40,761	231	40,184	7	(329)
Animal Drugs and Feeds	**702**	**136,912**	**713**	**137,964**	**714**	**137,750**	**712**	**141,566**	**(1)**	**4,654**
Center	413	83,707	433	84,651	430	84,219	423	87,846	(10)	4,139
Field Activities	289	53,205	280	53,313	284	53,531	289	53,720	9	515
Devices and Radiological Health	**1,611**	**322,672**	**1,609**	**322,636**	**1,636**	**324,647**	**1,582**	**320,544**	**(27)**	**(2,128)**
Center	1,139	241,475	1,154	241,443	1,174	242,953	1,116	240,064	(38)	(1,411)
Field Activities	472	81,197	455	81,193	462	81,694	466	80,480	11	(717)
National Center for Toxicological Research	**272**	**60,039**	**269**	**60,023**	**273**	**60,406**	**272**	**59,494**	**3**	**(545)**
FDA Headquarters	**756**	**162,559**	**718**	**153,519**	**795**	**163,554**	**782**	**173,111**	**64**	**10,552**
FDA White Oak Consolidation	**-**	**40,386**	**-**	**40,386**	**-**	**40,633**	**-**	**58,044**	**-**	**17,658**
Other Rent and Rent Related	**-**	**65,598**	**-**	**65,598**	**-**	**65,999**	**-**	**74,606**	**-**	**9,008**
GSA Rental Payments	**-**	**160,506**	**-**	**160,506**	**-**	**161,488**	**-**	**162,014**	**-**	**1,508**
SUBTOTAL, Salaries and Expenses	**9,927**	**2,497,021**	**9,664**	**2,497,473**	**9,922**	**2,512,303**	**9,940**	**2,548,905**	**276**	**51,884**
Buildings and Facilities (B&F)	**-**	**8,788**	**-**	**9,080**	**-**	**8,842**	**-**	**8,788**	**-**	**-**
FDA Building and Facilities	-	8,788	-	9,080	-	8,842	-	8,788	-	-
TOTAL	**9,927**	**2,505,809**	**9,664**	**2,506,553**	**9,922**	**2,521,145**	**9,940**	**2,557,693**	**276**	**51,884**
Non-Field Activities	5,449	1,324,796	5,321	1,324,215	5,516	1,332,904	5,457	1,336,912	136	12,116
Field Activities	4,478	905,735	4,343	906,768	4,406	911,279	4,483	917,329	140	11,594
Rent Activities, B&F, and White Oak	-	275,278	-	275,570	-	276,962	-	303,452	-	28,174

[1] FY 2012, FY 2013 and FY 2014 do not include an estimated 101 reimbursable, 1 CRADA, 42 PEPFAR, 12 IDDA FTE and the associated funds.

[2] FY 2012 Enacted reflects comparability adjustments for the Food and Veterinary Medicine Program reorganization approved in FY 2012, that started in FY 2013: -42 FTE and -$7.746M in the Foods Program; -8 FTE and -$1.109M in the Animal Drugs and Feeds Program; +50 FTE and +$8.855M in FDA Headquarters. FY 2012 Actuals do not reflect the reorganization.

[3] FY 2012 Actual includes $.459M in funds from the $2 million Gulf Oil Spill one time supplemental appropriation provided in PL. 111-212.

Food and Drug Administration
User Fees

(Dollars in Thousands)										
Program[1]	FY 2012 Enacted		FY 2012 Actuals		FY 2013[2] CR		FY 2014 Request		+/- FY 2012 Actual	+/- FY 2012 Enacted
	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Salaries and Expenses, Definite Appropriations:										
Current Law User Fees										
Prescription Drug User Fee Act (PDUFA)						0.00612				
Human Drugs (PDUFA)	**2,031**	**500,895**	**2,106**	**476,973**	**2,117**	**516,066**	**2,162**	**$545,434**	**56**	**44,539**
Center	1,980	490,877	2,059	470,444	2,070	505,745	2,115	$534,526	**56**	43,649
Field	51	10,018	47	6,529	47	10,321	47	$10,908	-	890
Biologics (PDUFA)	**360**	**105,217**	**406**	**87,663**	**406**	**108,406**	**414**	**$114,574**	**8**	**9,357**
Center	355	101,010	400	85,927	400	104,071	408	$109,993	**8**	8,983
Field	5	4,207	6	1,736	6	4,335	6	$4,581	-	374
FDA Headquarters (PDUFA)	**195**	**42,541**	**194**	**29,074**	**195**	**43,829**	**202**	**$46,323**	**8**	**3,782**
FDA Consolidation at White Oak	**-**	**3,595**	**-**	**3,415**	**-**	**3,669**	**-**	**$3,878**	**-**	**283**
Other Rent and Rent Related	**-**	**17,996**	**-**	**21,062**	**-**	**25,130**	**-**	**$26,794**	**-**	**8,798**
GSA Rental Payments	**-**	**31,928**	**-**	**18,742**	**-**	**21,569**	**-**	**$22,997**	**-**	**(8,931)**
Subtotal PDUFA	**2,586**	**702,172**	**2,706**	**636,929**	**2,718**	**718,669**	**2,778**	**$760,000**	**72**	**57,828**
Medical Device User Fee Act (MDUFA)										
Biologics (MDUFA)	**29**	**11,695**	**37**	**8,659**	**37**	**11,766**	**41**	**$10,493**	**4**	**(1,202)**
Center	28	11,183	37	8,231	37	11,251	40	$10,301	**3**	(882)
Field	1	512	-	428	-	515	1	$192	**1**	(320)
Devices and Radiological Health (MDUFA)	**221**	**34,237**	**338**	**54,061**	**338**	**34,447**	**366**	**$88,093**	**28**	**53,856**
Center	209	33,177	325	52,461	325	33,380	356	$86,180	31	53,003
Field	12	1,060	13	1,600	13	1,067	10	$1,913	(3)	853
FDA Headquarters (MDUFA)	**21**	**5,975**	**28**	**3,791**	**28**	**6,012**	**29**	**$6,485**	**1**	**510**
Other Rent and Rent Related	**-**	**1,390**	**-**	**1,470**	**-**	**1,399**	**-**	**$3,546**	**-**	**2,156**
GSA Rental Payments	**-**	**4,308**	**-**	**2,347**	**-**	**4,334**	**-**	**$6,216**	**-**	**1,908**
Subtotal (MDUFA)	**271**	**57,605**	**403**	**70,328**	**403**	**57,958**	**436**	**$114,833**	**33**	**57,228**
Animal Drug User Fee Act (ADUFA)[1]										
Animal Drugs and Feeds	**68**	**19,576**	**63**	**14,864**	**68**	**19,696**	**68**	**$21,240**	**5**	**1,664**
Center	66	19,261	62	14,723	67	19,379	67	$20,768	**5**	1,507
Field	2	315	1	141	1	317	1	$472	-	157
FDA Headquarters (ADUFA)	**4**	**873**	**4**	**638**	**4**	**878**	**4**	**$944**	**-**	**71**
Other Rent and Rent Related	**-**	**204**	**-**	**76**	**-**	**205**	**-**	**$236**	**-**	**32**
GSA Rental Payments	**-**	**1,115**	**-**	**559**	**-**	**1,122**	**-**	**$1,180**	**-**	**65**
Subtotal (ADUFA)	**72**	**21,768**	**67**	**16,137**	**72**	**21,901**	**72**	**$23,600**	**5**	**1,832**
Animal Generic Drug User Fee Act (AGDUFA)[1]										
Animal Drugs and Feeds	**21**	**5,058**	**20**	**4,081**	**21**	**5,089**	**21**	**$6,522**	**1**	**1,464**
Center	20	4,898	20	4,081	20	4,928	20	$6,302	-	1,404
Field	1	160	-	-	1	161	1	$220	1	60
FDA Headquarters (AGDUFA)	**1**	**228**	**1**	**168**	**1**	**230**	**1**	**$293**	**-**	**65**
Other Rent and Rent Related	**-**	**80**	**-**	**18**	**-**	**80**	**-**	**$73**	**-**	**(7)**
GSA Rental Payments	**-**	**340**	**-**	**99**	**-**	**342**	**-**	**$440**	**-**	**100**
Subtotal (AGDUFA)	**22**	**5,706**	**21**	**4,366**	**22**	**5,741**	**22**	**$7,328**	**1**	**1,622**
Voluntary Qualified Importer Program (VQIP) User Fee	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**$0**	**-**	-
Family Smoking Prevention and Tobacco Control Act										
Center for Tobacco Products	**392**	**454,751**	**379**	**277,136**	**523**	**457,534**	**640**	**$501,476**	**261**	**46,725**
Center	366	448,501	346	271,695	482	451,246	570	$486,487	224	37,986
Field	26	6,250	33	5,441	41	6,288	70	$14,989	37	8,739
FDA Headquarters	**34**	**15,196**	**47**	**11,594**	**34**	**15,289**	**52**	**$19,500**	5	**4,304**
Other Rent and Rent Related	**-**	**1,550**	**-**	**1,579**	**-**	**1,559**	**-**	**$3,050**	-	**1,500**
GSA Rental Payments	**-**	**5,503**	**-**	**5,402**	**-**	**5,537**	**-**	**$9,974**	-	**4,471**
Subtotal	**426**	**477,000**	**426**	**295,711**	**557**	**479,919**	**692**	**$534,000**	**266**	**57,000**

Food and Drug Administration
User Fees

Indefinite User Fees										
Mammography Quality and Standards Act (MQSA)										
Devices and Radiological Health	**34**	**19,080**	**39**	**14,257**	**39**	**19,080**	**39**	**$19,080**	**-**	**-**
Center	26	6,003	31	5,122	31	6,003	31	$6,003	-	-
Field Activities	8	13,077	8	9,135	8	13,077	8	$13,077	-	-
FDA Headquarters (MQSA)	**2**	**238**	**2**	**270**	**2**	**238**	**2**	**$238**	**-**	-
Subtotal (MQSA)	**36**	**19,318**	**41**	**14,527**	**41**	**19,318**	**41**	**$19,318**	**-**	-
Export Certification	**15**	**3,337**	**18**	**4,214**	**18**	**4,604**	**22**	**$4,604**	**4**	1,267
Priority Review Vouchers (PRV) 3/	**-**	**4,582**	**-**	**-**	**-**	**-**	**-**	**$0**	**-**	(4,582)
Color Certification Fund	**37**	**7,843**	**36**	**7,396**	**37**	**7,843**	**37**	**$7,843**	**1**	-
Generic Drug User Fee (GDUFA)										
Human Drugs	**-**	**-**	**-**	**-**	**400**	**254,542**	**617**	**$260,498**	**617**	**260,498**
Center	-	-			250	202,731	444	$207,475	444	207,475
Field	-	-			150	51,811	173	$53,023	173	53,023
Biologics (GDUFA)							**3**	**$774**	**3**	**774**
Center	-						3	$774	**3**	774
Field	-						-	$0	**-**	-
FDA Headquarters (GDUFA)	**-**	**-**			**50**	**24,196**	**70**	**$23,988**	**70**	**23,988**
Other Rent and Rent Related	**-**	**-**			**-**	**6,447**	**-**	**$6,598**	**-**	**6,598**
GSA Rental Payments	**-**	**-**			**-**	**13,815**	**-**	**$14,138**	**-**	**14,138**
Subtotal	**-**	**-**	**-**	**-**	**450**	**299,000**	**690**	**$305,996**	**690**	**305,996**
Biosimilar User Fee Act (BsUFA)										
Human Drugs (BsUFA)	**-**	**-**	**-**	**-**	**64**	**16,594**	**64**	**$16,998**	**64**	**16,998**
Center	-	-			59	15,304	59	$15,676	**59**	15,676
Field	-	-			5	1,290	5	$1,322	**5**	1,322
Biologics (BsUFA)	-	-	-	-	**3**	**774**	**3**	**$774**	**3**	**774**
Center	-	-			3	774	3	$774	**3**	774
Field	-	-			-	-	-	$0	**-**	-
FDA Headquarters (BsUFA)	**-**	**-**			**5**	**1,290**	**5**	**$1,321**	**5**	1,321
Other Rent and Rent Related	-	-			-	576	-	$590	**-**	590
GSA Rental Payments	-	-			-	1,008	-	$1,033	**-**	1,033
Subtotal BsUFA	**-**	**-**	**-**	**-**	**72**	**20,242**	**72**	**$20,716**	**72**	**20,716**
Food Reinspection User Fee										
Office of Regulatory Affairs	**66**	**9,375**	**-**	**-**	**66**	**9,433**	**66**	**$9,800**	**66**	**425**
Foods Program Estimate	48	6,825			48	6,867	48	$7,134	48	309
Animal Drugs and Feeds Program Estimate	18	2,550			18	2,566	18	$2,666	18	116
FDA Headquarters	**7**	**3,395**			**7**	**3,416**	**7**	**$3,549**	**7**	154
Other Rent and Rent Related	**-**	**592**			**-**	**595**	**-**	**$619**	**-**	27
GSA Rental Payments	**-**	**1,338**			**-**	**1,346**	**-**	**$1,399**	**-**	61
Subtotal	**73**	**14,700**	**-**	**-**	**73**	**14,790**	**73**	**$15,367**	**73**	**667**
Food and Feed Recall User Fee										
Foods	**25**	**9,861**	**-**	**-**	**25**	**9,922**	**25**	**$10,308**	**25**	**447**
Center	2	464			2	467	2	$485	2	21
Field	23	9,397			23	9,455	23	$9,823	23	426
Animal Drugs and Feeds	**4**	**1,160**	**-**	**-**	**4**	**1,167**	**4**	**$1,213**	**4**	**53**
Center	2	521			2	524	2	$545	2	24
Field	2	639			2	643	2	$668	2	29
FDA Headquarters	**2**	**661**			**2**	**665**	**2**	**$691**	**2**	30
Other Rent and Rent Related	**-**	**248**			**-**	**249**	**-**	**$259**	**-**	11
GSA Rental Payments	**-**	**434**			**-**	**437**	**-**	**$454**	**-**	20
Subtotal	**31**	**12,364**	**-**	**-**	**31**	**12,440**	**31**	**$12,925**	**31**	**561**

Food and Drug Administration
User Fees

Proposed User Fees:										
Medical Products Reinspection User Fee										
Office of Regulatory Affairs	**-**	**-**	**-**	**-**	**-**	**-**	**46**	**$7,170**	**46**	**7,170**
Human Drugs Program Estimate	**-**	**-**			-	-	18	$2,804	18	2,804
Biologics Program Estimate	**-**	**-**			-	-	3	$572	3	572
Animal Drugs Program Estimate	**-**	**-**			-	-	1	$143	1	143
Devices and Radiological Health Program Estimate	**-**	**-**			-	-	24	$3,651	24	3,651
FDA Headquarters	**-**	**-**			-	-	**10**	**$6,293**	**10**	**6,293**
Other Rent and Rent Related	**-**	**-**			**-**	**-**	**-**	**$486**	**-**	**486**
GSA Rental Payments	**-**	**-**			**-**	**-**	**-**	**$1,094**	**-**	**1,094**
Subtotal	**-**	**-**	**-**	**-**	**-**	**-**	**56**	**$15,043**	**56**	**15,043**
International Courier User Fee										
Office of Regulatory Affairs	**-**	**-**	**-**	**-**	**-**	**-**	**20**	**$4,904**	**20**	**4,904**
Foods Program Estimate	**-**	**-**			-	-	3	$735	3	735
Human Drugs Program Estimate	**-**	**-**			-	-	2	$491	2	491
Devices and Radiological Health Program Estimate	**-**	**-**			-	-	15	$3,678	15	3,678
FDA Headquarters	**-**	**-**			**-**	**-**	**1**	**$295**	**1**	**295**
Other Rent and Rent Related	**-**	**-**			**-**	**-**	**-**	**$180**	**-**	**180**
GSA Rental Payments	**-**	**-**			**-**	**-**	**-**	**$313**	**-**	**313**
Subtotal	**-**	**-**	**-**	**-**	**-**	**-**	**21**	**$5,692**	**21**	**5,692**
Food Facility Registration and Inspection User Fee:										
Foods	-	-	-	-	**-**	**-**	**48**	**$49,657**	**48**	**49,657**
Center	-	-			-	-	28	$22,820	28	22,820
Field Activities	-	-			-	-	20	$26,837	20	26,837
Animal Drugs and Feeds	-	-	-	-	**-**	**-**	**8**	**$2,544**	**8**	**2,544**
Center	-	-			-	-	6	$1,526	6	1,526
Field Activities	-	-			-	-	2	$1,018	2	1,018
FDA Headquarters	-	-			**-**	**-**	**13**	**$4,486**	**13**	**4,486**
Other Rent and Rent Related	-	-			**-**	**-**	**-**	**$811**	**-**	**811**
GSA Rental Payments	-	-			**-**	**-**	**-**	**$1,438**	**-**	**1,438**
Subtotal	**-**	**-**	**-**	**-**	**-**	**-**	**69**	**$58,936**	**69**	**58,936**
Food Import User Fee:										
Foods							**237**	**$134,745**	**237**	**134,745**
Center							10	$13,810	10	13,810
Field Activities							227	$120,935	227	120,935
Animal Drugs and Feeds							**32**	**$14,859**	**32**	**14,859**
Center							6	$1,439	6	1,439
Field Activities							26	$13,420	26	13,420
FDA Headquarters							**32**	**$9,278**	**32**	**9,278**
Other Rent and Rent Related							**-**	**$2,478**	**-**	**2,478**
GSA Rental Payments							**-**	**$4,330**	**-**	**4,330**
Subtotal							**301**	**$165,690**	**301**	**165,690**
Cosmetics User Fee:										
Foods	**-**	**-**	**-**	**-**	**-**	**-**	**60**	**$16,660**	**60**	**16,660**
Center	-	-			-	-	42	$12,253	42	12,253
Field	-	-			-	-	18	$4,407	18	4,407
FDA Headquarters	-	-			**-**	**-**	**3**	**$1,000**	**3**	**1,000**
Other Rent and Rent Related	-	-			-	**-**	-	**$514**	**-**	**514**
GSA Rental Payments	-	-			-	**-**	-	**$900**	**-**	**900**
Subtotal	**-**	**-**	**-**	**-**	**-**	**-**	**63**	**$19,074**	**63**	**19,074**
Food Contact Substance Notification User Fee										
Foods	**-**	**-**	**-**	**-**	**-**	**-**	**7**	**$4,548**	**7**	**4,548**
Center	-	-			-	-	7	$4,548	7	4,548
Field	-	-			**-**	-	**-**	$0	-	-
FDA Headquarters	-	-			**-**	**-**	**1**	**$272**	**1**	**272**
Other Rent and Rent Related	-	-			-	**-**	-	**$65**	**-**	**65**
GSA Rental Payments	-	-			-	**-**	-	**$114**	**-**	**114**
Subtotal	**-**	**-**	**-**	**-**	**-**	**-**	**8**	**$4,999**	**8**	**4,999**
Proposed User Fees total	**-**	**-**	**-**	**-**	**-**	**-**	**518**	**$269,434**	**518**	**269,434**
Current Law User Fees total:	**3,377**	**$1,264,251**	**3,623**	**$1,023,471**	**3,772**	**$1,284,188**	**4,000**	**$1,439,761**	**377**	**175,510**
Indefinite User Fees total	**192**	**$62,144**	**95**	**$26,137**	**722**	**$378,237**	**966**	**$386,769**	**871**	**324,625**
Total User Fees	**3,569**	**1,326,395**	**3,718**	**1,049,608**	**4,494**	**1,662,425**	**5,484**	**$2,095,964**	**1,766**	**769,569**

[1] ADUFA and AGDUFA authorizations expire on October 1, 2013. Legislative proposals to reauthorize ADUFA and AGDUFA were transmitted to Congress in February 2013. The fee revenue levels in FY 2014 for ADUFA and AGDUFA are based on the legislative proposals.

[2] Spending authority has been adjusted pursuant to PL 112-175, Section 101(c) for the applicable user fee programs.

[3] The program requires a sponsor to notify FDA of its intent to submit a PRV application 365 days prior to the submission. FDA has not yet received a notification for FY 2014. Therefore, FDA does not anticipate receiving PRV fees in FY 2014.

Food and Drug Administration
Program Level

(Dollars in Thousands)

Program[1,2]	FY 2012 Enacted FTE	FY 2012 Enacted $000	FY 2012 Actuals FTE	FY 2012 Actuals $000	FY 2013 [3] CR FTE	FY 2013 [3] CR $000	FY 2014 Request FTE	FY 2014 Request $000	+/- FY 2012 Actual FTE	+/- FY 2012 Enacted $000
Salaries and Expenses:										
Foods 4/	**3,715**	**875,001**	**3,546**	**866,920**	**3,684**	**880,357**	**4,110**	**1,106,604**	**564**	**231,603**
Center	899	257,952	882	265,158	913	259,531	994	320,324	112	62,372
Field	2,816	617,049	2,664	601,762	2,771	620,826	3,116	786,280	452	169,231
Human Drug	**4,071**	**978,705**	**4,039**	**954,596**	**4,578**	**1,267,937**	**4,882**	**1,292,175**	**843**	**313,470**
Center	3,281	838,694	3,272	818,077	3,644	1,073,726	3,917	1,097,091	645	258,397
Field	790	140,011	767	136,519	934	194,211	965	195,084	198	55,073
Biologics	**1,294**	**329,136**	**1,319**	**308,620**	**1,342**	**334,469**	**1,356**	**337,946**	**37**	**8,810**
Center	1,055	283,904	1,089	265,946	1,108	288,858	1,115	292,417	26	8,513
Field	239	45,232	230	42,674	234	45,611	241	45,529	11	297
Animal Drugs and Feeds	**813**	**165,256**	**796**	**156,909**	**825**	**166,268**	**864**	**190,753**	**68**	**25,497**
Center	501	108,387	515	103,455	519	109,050	524	118,426	9	10,039
Field	312	56,869	281	53,454	306	57,218	340	72,327	59	15,458
Devices and Radiological Health	**1,866**	**375,989**	**1,986**	**390,954**	**2,013**	**378,174**	**2,026**	**435,046**	**40**	**59,057**
Center	1,374	280,655	1,510	299,026	1,530	282,336	1,503	332,247	(7)	51,592
Field	492	95,334	476	91,928	483	95,838	523	102,799	47	7,465
National Center for Toxicological Research	**272**	**60,039**	**269**	**60,023**	**273**	**60,406**	**272**	**59,494**	**3**	**(545)**
Tobacco Act Program	**392**	**454,751**	**379**	**277,136**	**523**	**457,534**	**640**	**501,476**	**261**	**46,725**
Center	366	448,501	346	271,695	482	451,246	570	486,487	224	37,986
Field	26	6,250	33	5,441	41	6,288	70	14,989	37	8,739
FDA Headquarters	**1,022**	**231,666**	**994**	**199,054**	**1,123**	**259,597**	**1,216**	**298,067**	**222**	**66,401**
FDA White Oak Consolidation	-	**43,981**	-	**43,801**	-	**44,302**	-	**61,922**	**-**	**17,941**
Other Rent and Rent Related	-	**87,658**	-	**89,803**	-	**102,239**	-	**120,905**	**-**	**33,247**
GSA Rental Payments	-	**205,472**	-	**187,655**	-	**210,998**	-	**228,034**	**-**	**22,562**
TOTAL, Salaries & Expenses	**13,444**	**3,807,654**	**13,328**	**3,535,471**	**14,361**	**4,162,281**	**15,365**	**4,632,422**	**2,038**	**824,768**
Export Certification	**15**	**3,337**	**18**	**4,214**	**18**	**4,604**	**22**	**4,604**	**4**	**1,267**
Color Certification Fund	**37**	**7,843**	**36**	**7,396**	**37**	**7,843**	**37**	**7,843**	**1**	**-**
Priority Review Voucher User Fee	-	**4,582**	-	-	-	-	-	-	-	**(4,582)**
Buildings and Facilities	-	**8,788**	-	**9,080**	-	**8,842**	-	**8,788**	-	-
FDA Building and Facilities	-	8,788	-	9,080	-	8,842	-	8,788	-	-
TOTAL PROGRAM LEVEL	**13,496**	**3,832,204**	**13,382**	**3,556,161**	**14,416**	**4,183,570**	**15,424**	**4,653,657**	**2,043**	**821,453**
Non-Field Activities	8,821	2,525,560	8,931	2,294,044	9,647	2,797,197	10,169	3,017,000	1,238	491,440
Field Activities	4,675	960,745	4,451	931,778	4,769	1,019,992	5,255	1,217,008	804	256,263
Rent Activities, B&F, and White Oak	-	345,899	-	330,339	-	366,381	-	419,649	-	73,750
Less User Fees:										
Prescription Drugs (PDUFA)	2,586	702,172	2,706	636,929	2,718	718,669	2,778	760,000	72	57,828
Medical Devices (MDUFA)	271	57,605	403	70,328	403	57,958	436	114,833	33	57,228
Food Reinspection User Fee	73	14,700	-	-	73	14,790	73	15,367	73	667
Food and Feed Recall User Fee:	31	12,364	-	-	31	12,440	31	12,925	31	561
Voluntary Qualified Importer Program (VQIP) User Fee	-	-	-	-	-	-	-	-	-	-
Family Smoking Prevention and Tobacco Control Act	426	477,000	426	295,711	557	479,919	692	534,000	266	57,000
Mammography Quality (MQSA)	36	19,318	41	14,527	41	19,318	41	19,318	-	-
Color Certification Fund	37	7,843	36	7,396	37	7,843	37	7,843	1	-
Export Certification	15	3,337	18	4,214	18	4,604	22	4,604	4	1,267
Priority Review Voucher User Fee	-	4,582	-	-	-	-	-	-	-	(4,582)
Generic Drug (GDUFA)	-	-	-	-	450	299,000	690	305,996	690	305,996
Biosimilar User Fee	-	-	-	-	72	20,242	72	20,716	72	20,716
Animal Drugs (ADUFA) 5/	72	21,768	67	16,137	72	21,901	72	23,600	5	1,832
Animal Generic Drug (AGDUFA) 5/	22	5,706	21	4,366	22	5,741	22	7,328	1	1,622
Food Facility Registration and Inspection Fee	-	-	-	-	-	-	69	58,936	69	58,936
Food Import User Fee							301	165,690	301	165,690
Medical Products Reinspection User Fee	-	-	-	-	-	-	56	15,043	56	15,043
International Courier User Fee	-	-	-	-	-	-	21	5,692	21	5,692
Cosmetics User Fee	-	-	-	-	-	-	63	19,074	63	19,074
Food Contact Substance Notification User Fee	-	-	-	-	-	-	8	4,999	8	4,999
SUBTOTAL User Fees	**3,569**	**1,326,395**	**3,718**	**1,049,608**	**4,494**	**1,662,425**	**5,484**	**2,095,964**	**1,766**	**769,569**
TOTAL USER FEES	**3,569**	**1,326,395**	**3,718**	**1,049,608**	**4,494**	**1,662,425**	**5,484**	**2,095,964**	**1,766**	**769,569**
TOTAL BUDGET AUTHORITY	**9,928**	**2,505,809**	**9,664**	**2,506,553**	**9,922**	**2,521,145**	**9,940**	**2,557,693**	**276**	**51,884**

[1] FY 2012, FY 2013 and FY 2014 do not include an estimated 101 reimbursable, 1 CRADA, 42 PEPFAR, 12 IDDA FTE and the associated funds.

[2] FY 2012 Enacted reflects comparability adjustments for the Food and Veterinary Medicine Program reorganization approved in FY 2012, that started in FY 2013: -42 FTE and -$7.746M in the Foods Program; -8 FTE and -$1.109M in the Animal Drugs and Feeds Program; +50 FTE and +$8.855M in FDA Headquarters. FY 2012 Actuals do not reflect the reorganization.

[3] Spending authority has been adjusted pursuant to PL 112-175, Section 101(c) for the applicable user fee programs.

[4] FY 2012 Actual includes $.459M in funds from the $2 million Gulf Oil Spill one time supplemental appropriation provided in PL. 111-212.

[5] ADUFA and AGDUFA authorizations expire on October 1, 2013. Legislative proposals to reauthorize ADUFA and AGDUFA were transmitted to Congress in February 2013. The fee revenue levels in FY 2014 for ADUFA and AGDUFA are based on the legislative proposals.

Crosswalk to Summary of Changes:

Budget Authority

(Dollars in Thousands)

Program [1]	FY 2012 [2]		FY 2014 Pay Increase		Initiatives						Rent and Infrastructure	Base Adjustment [3]		FY 2014 President's Budget	
					Food Safety Modernization		Inspections in China		Medical Counter-measures						
	Enacted FTE	Enacted $000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	$000	FTE	$000	FTE	$000
Foods	**3,642**	**858,315**		**3,764**	**40**	**20,738**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**3,682**	**882,817**
Center	897	257,488		1,127	8	7,793	0	0	0	0	0		0	905	266,408
Field Activities	2,745	600,827		2,637	32	12,945	0	0	0	0	0		0	2,777	616,409
Human Drugs	**2,040**	**477,810**		**2,099**	**0**	**0**	**0**	**0**	**0**	**840**	**0**	**-21**	**-14,799**	**2,019**	**465,950**
Center	1,301	347,817		1,528	0		0	0	0	840	0	-2	-10,771	1,299	339,414
Field Activities	739	129,993		571	0		0	0	0	0	0	-19	-4,028	720	126,536
Biologics	**905**	**212,224**		**932**	**0**	**0**	**0**	**0**	**0**	**252**	**0**	**-13**	**-2,649**	**892**	**210,759**
Center	672	171,711		755	0		0	0	0	252	0	-11	-2,143	661	170,575
Field Activities	233	40,513		177	0		0	0	0	0	0	-2	-506	231	40,184
Animal Drugs and Feeds	**702**	**136,912**		**598**	**12**	**4,439**	**0**	**0**	**0**	**0**	**0**	**-2**	**-383**	**712**	**141,566**
Center	413	83,707		365	11	4,009	0	0	0	0	0	-1	-235	423	87,846
Field Activities	289	53,205		233	1	430	0	0	0	0	0	-1	-148	289	53,720
Devices and Radiological Health	**1,611**	**322,672**		**1,417**	**0**	**0**	**0**	**0**	**0**	**723**	**0**	**-29**	**-4,268**	**1,582**	**320,544**
Center	1,139	241,475		1,060	0	0	0	0	0	723	0	-23	-3,194	1,116	240,064
Field Activities	472	81,197		357	0	0	0	0	0	0	0	-6	-1,074	466	80,480
National Center for Toxicological Research	**272**	**60,039**		**263**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**-808**	**272**	**59,494**
FDA Headquarters	**756**	**162,559**		**727**	**7**	**5,811**	**19**	**10,000**		**1,299**	**0**	**0**	**-7,285**	**782**	**173,111**
FDA White Oak Consolidation	**-**	**40,386**		0	0	**0**	0	**0**	0	**0**	**17,658**	**0**	**0**	**0**	**58,044**
Other Rent and Rent Related	**-**	**65,598**		0	0	**6,328**	0	**0**		**396**	**2,284**	**0**	**0**	**0**	**74,606**
GSA Rental Payments	**-**	**160,506**		0	0	**1,508**	0	**0**		**0**	**0**	**0**	**0**	**0**	**162,014**
SUBTOTAL, Salaries and Expenses	**9,927**	**2,497,021**		**9,800**	**59**	**38,824**	19	**10,000**	0	**3,510**	**19,942**	**-65**	**-30,192**	**9,940**	**2,548,905**
Buildings and Facilities	**-**	**8,788**		**0**	0	**0**	0	**0**	0	**0**	**0**	**0**	**0**	**0**	**8,788**
FDA Building and Facilities	-	8,788		0	0	0	0	0	0	0	0	**0**	**0**	0	8,788
TOTAL	**9,927**	**2,505,809**		**9,800**	**59**	**38,824**	**19**	**10,000**	**0**	**3,510**	**19,942**	**-65**	**-30,192**	**9,940**	**2,557,693**
Non-Field Activities	5,449	1,324,796		5,825	**26**	**17,613**	19	10,000	0	3,114	0	-37	**-24,436**	5,457	1,336,912
Field Activities	4,478	905,735		3,975	**33**	**13,375**	0	0	0	0	0	-28	**-5,756**	4,483	917,329
Rent Activities, B&F, and White Oak	-	275,278		0	0	**7,836**	0	0	0	396	19,942	**0**	**0**	0	303,452

[1] FY 2012, FY 2013 and FY 2014 do not include an estimated 101 reimbursable, 1 CRADA, 42 PEPFAR, 12 IDDA FTE and the associated funds.

[2] FY 2012 Enacted reflects comparability adjustments for the Food and Veterinary Medicine Program reorganization approved in FY 2012, that started in FY 2013: -42 FTE and -$7.746M in the Foods Program; -8 FTE and -$1.109M in the Animal Drugs and Feeds Program; +50 FTE and +$8.855M in FDA Headquarters.

[3] Base Adjustment levels include FTE reductions for pay absorption under FY 2013 CR.

User Fees
(Dollars in Thousands)

Program	FY 2012		Current law User Fees												Indefinite User Fees								Program	Indefinite User Fees								Proposed User Fees										Sub-total Increases above FY 2012		FY 2014 Request	
			PDUFA		MDUFA		ADUFA[1]		AGDUFA[1]		VQIP		Tobacco		MQSA		Color Certification		Export Cert		Priority Review Vouchers			Generic Drug User Fee (GDUFA)		Biosimilar User Fee (BSUFA)		Food Reinspection		Food and Feed Recall		Food Facility Registration and Inspection Fee		Food Import User Fee		Medical Products Reinspection		International Courier		Cosmetics		Food Contact Substance Notification					
	Actual FTE	Enacted $000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000		FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	Actual FTE	Enacted $000	FTE	$000
Foods	**0**	**$16,686**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	**Foods**	-	-	-	-	**48**	**309**	**25**	**447**	**48**	**49,657**	**237**	**134,745**	-	-	**3**	**735**	**60**	**16,660**	**7**	**4,548**	**428**	**207,101**	**428**	**223,787**
Center	0	464	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	*Center*	-	-	-	-	-	-	2	21	28	22,820	10	13,810	-	-	-	-	42	12,253	7	4,548	89	53,452	89	53,916
Field Activities	0	16,222	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	*Field Activities*	-	-	-	-	48	309	23	426	20	26,837	227	120,935	-	-	3	735	18	4,407	-	-	339	153,649	339	169,871
Human Drugs	**2,106**	**$500,895**	**56**	**44,539**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	**Human Drugs**	**617**	**260,498**	**64**	**16,998**	-	-	-	-	-	-	-	-	**18**	**2,804**	**2**	**491**	-	-	-	-	**757**	**325,330**	**2,863**	**826,225**
Center	2,059	490,877	56	43,649	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	*Center*	444	207,475	59	15,676	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	559	266,800	2,618	757,677
Field Activities	47	10,018	-	890	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	*Field Activities*	173	53,023	5	1,322	-	-	-	-	-	-	-	-	18	2,804	2	491	-	-	-	-	198	58,530	245	68,548
Biologics	**443**	**$116,912**	**8**	**9,357**	**4**	**(1,202)**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	**Biologics**	**3**	**774**	**3**	**774**	-	-	-	-	-	-	-	-	**3**	**572**	-	-	-	-	-	-	**21**	**10,275**	**464**	**127,187**
Center	437	112,193	8	8,983	3	(882)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	*Center*	3	774	3	774	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	17	9,649	454	121,842
Field Activities	6	4,719	-	374	1	(320)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	*Field Activities*	-	-	-	-	-	-	-	-	-	-	-	-	3	572	-	-	-	-	-	-	4	626	10	5,345
Animal Drugs and Feeds	**83**	**$28,344**	-	-	-	-	**5**	**1,664**	**1**	**1,464**	-	-	-	-	-	-	-	-	-	-	-	-	**Animal Drugs and Feeds**	-	-	-	-	**18**	**116**	**4**	**53**	**8**	**2,544**	**32**	**14,859**	**1**	**143**	-	-	-	-	-	-	**69**	**20,843**	**152**	**49,187**
Center	82	24,680	-	-	-	-	5	1,507	-	1,404	-	-	-	-	-	-	-	-	-	-	-	-	*Center*	-	-	-	-	-	-	2	24	6	1,526	6	1,439	-	-	-	-	-	-	-	-	19	5,900	101	30,580
Field Activities	1	3,664	-	-	-	-	-	157	1	60	-	-	-	-	-	-	-	-	-	-	-	-	*Field Activities*	-	-	-	-	18	116	2	29	2	1,018	26	13,420	1	143	-	-	-	-	-	-	50	14,943	51	18,607
Devices and Radiological Health	**377**	**$53,317**	-	-	**28**	**53,856**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	**Devices and Radiological Health**	-	-	-	-	-	-	-	-	-	-	-	-	**24**	**3,651**	**15**	**3,678**	-	-	-	-	**67**	**61,185**	**444**	**114,502**
Center	356	39,180	-	-	31	53,003	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	*Center*	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	31	53,003	387	92,183
Field Activities	21	14,137	-	-	(3)	853	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	*Field Activities*	-	-	-	-	-	-	-	-	-	-	-	-	24	3,651	15	3,678	-	-	-	-	36	8,182	57	22,319
National Center for Toxicological Research	**0**	**0**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	**National Center for Toxicological Research**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Tobacco	**379**	**$454,751**	-	-	-	-	-	-	-	-	-	-	**261**	**46,725**	-	-	-	-	-	-	-	-	**Tobacco**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	**261**	**46,725**	**640**	**501,476**
Center	346	448,501	-	-	-	-	-	-	-	-	-	-	224	37,986	-	-	-	-	-	-	-	-	*Center*	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	224	37,986	570	466,487
Field	33	6,250	-	-	-	-	-	-	-	-	-	-	37	8,739	-	-	-	-	-	-	-	-	*Field*	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	37	8,739	70	14,989
FDA Headquarters	**276**	**69,107**	**8**	**3,782**	**1**	**510**	-	**71**	-	**65**	-	-	**5**	**4,304**	-	-	-	-	-	-	-	-	**FDA Headquarters**	**70**	**23,988**	**5**	**1,321**	**7**	**154**	**2**	**30**	**13**	**4,486**	**32**	**9,278**	**10**	**6,293**	**1**	**295**	**3**	**1,000**	**1**	**272**	**158**	**55,849**	**434**	**124,956**
FDA White Oak Consolidation	**0**	**3,595**	-	**283**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	**FDA White Oak Consolidation**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	**283**	-	**3,878**
Other Rent and Rent Related	**0**	**22,060**	-	**8,798**	-	**2,156**	-	**32**	-	**(7)**	-	-	-	**1,500**	-	-	-	-	-	-	-	-	**Other Rent and Rent Related**	-	**6,598**	-	**590**	-	**27**	-	**11**	-	**811**	-	**2,478**	-	**486**	-	**180**	-	**514**	-	**65**	-	**24,239**	-	**46,299**
GSA Rental Payments	**0**	**44,966**	-	**(8,931)**	-	**1,908**	-	**65**	-	**100**	-	-	-	**4,471**	-	-	-	-	-	-	-	-	**GSA Rental Payments**	-	**14,138**	-	**1,033**	-	**61**	-	**20**	-	**1,438**	-	**4,330**	-	**1,094**	-	**313**	-	**900**	-	**114**	-	**21,054**	-	**66,020**
Export Certification	**18**	**3,337**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	**4**	**1,267**	-	-	**Export Certification**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	**4**	**1,267**	**22**	**4,604**
Color Certification	**36**	**7,843**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	**1**	-	-	-	-	-	**Color Certification**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	**1**	-	**37**	**7,843**
Priority Review Vouchers	**0**	**4,582**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	**(4,582)**		**Priority Review Vouchers**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	**(4,582)**	-	-
Total	**3,718**	**1,326,395**	**72**	**57,828**	**33**	**57,228**	**5**	**1,832**	**1**	**1,622**	-	-	**266**	**57,000**	-	-	**1**	-	**4**	**1,267**	**(4,582)**		**Total**	**690**	**305,996**	**72**	**20,716**	**73**	**667**	**31**	**561**	**69**	**58,936**	**301**	**165,690**	**56**	**15,043**	**21**	**5,692**	**63**	**19,074**	**8**	**4,999**	**1,766**	**769,569**	**5,484**	**2,095,964**
Non-Field	3,610	1,200,764	72	56,414	35	52,631	5	1,578	-	1,469	-	-	229	42,290	-	-	1	-	4	1,267	(4,582)		Non-Field	517	232,237	67	17,771	7	154	6	75	47	28,832	48	24,527	10	6,293	1	295	45	13,253	8	4,820	1,102	479,324	4,712	1,680,088
Field	108	55,010	-	1,264	(2)	533	-	157	1	60	-	-	37	8,739	-	-	-	-	-	-	-		Field	173	53,023	5	1,322	66	425	25	455	22	27,855	253	134,355	46	7,170	20	4,904	18	4,407	-	-	664	244,669	772	299,679
Rent Activities, B&F, and White Oak	-	70,621	-	150	-	4,064	-	97	-	93	-	-	-	5,971	-	-	-	-	-	-	-		Rent Activities, B&F, and White Oak	-	20,736	-	1,623	-	88	-	31	-	2,249	-	6,808	-	1,580	-	493	-	1,414	-	179	-	45,576	-	116,197

[1] ADUFA and AGDUFA authorizations expire on October 1, 2013. Legislative proposals to reauthorize ADUFA and AGDUFA were transmitted to Congress in February 2013. The fee revenue levels in FY 2014 for ADUFA and AGDUFA are based on the legislative proposals.

Narrative by Activity:

Foods Program

The following table displays the funding and full time equivalent (FTE) staffing levels for FY 2012 through FY 2014.

FDA Program Resource Table

Food Program

(dollars in thousands)

	FY 2012 Enacted	FY 2012 Actual	FY 2013 CR	FY 2014 President's Budget	FY 2014 '+/- FY 2012
Program Level	**$875,001**	**$866,920**	**$880,357**	**$1,106,604**	**$231,603**
Center	$257,952	$265,158	$259,531	$320,324	$62,372
FTE	899	882	913	994	112
Field	$617,049	$601,762	$620,826	$786,280	$169,231
FTE	2,816	2,664	2,771	3,116	452
Program Level FTE	**3,715**	**3,546**	**3,684**	**4,110**	**395**
Budget Authority	**$858,315**	**$866,920**	**$863,568**	**$882,817**	**$24,502**
Center	$257,488	$265,158	$259,064	$266,408	$8,920
Field	$600,827	$601,762	$604,504	$616,409	$15,582
Budget Authority FTE	**3,642**	**3,546**	**3,611**	**3,682**	**136**
Center	897	882	911	905	23
Field	2,745	2,664	2,700	2,777	113
User Fees	**$16,686**	-	**$16,789**	**$223,787**	**$207,101**
Reinspection	**$6,825**	-	**$6,867**	**$7,134**	**$309**
Field	$6,825	-	$6,867	$7,134	$7,134
FTE	48	-	48	48	48
Voluntary Qualified Importer Program Fee	-	-	-	-	-
Recall User Fee	**$9,861**	-	**$9,922**	**$10,308**	**$447**
Center	464	-	467	485	21
FTE	2	-	2	2	2
Field	9,397	-	9,455	9,823	426
FTE	23	-	23	23	23
Food Establishment Reg. and Inspect. Fee	-	-	-	**$49,657**	**$49,657**
Center	-	-	-	22,820	22,820
FTE	-	-	-	28	28
Field	-	-	-	$26,837	$26,837
FTE	-	-	-	20	20
Food Importer User Fee	-	-	-	**$134,745**	**$134,745**
Center	-	-	-	13,810	13,810
FTE	-	-	-	10	10
Field	-	-	-	120,935	120,935
FTE	-	-	-	227	227
Cosmetics User Fee	-	-	-	**$16,660**	**$16,660**
Center	-	-	-	12,253	12,253
FTE	-	-	-	42	42
Field	-	-	-	4,407	4,407
FTE	-	-	-	18	18
Food Contact Notification User fee	-	-	-	**$4,548**	**$4,548**
Center	-	-	-	4,548	4,548
FTE	-	-	-	7	7
Field	-	-	-	-	-
FTE	-	-	-	-	-
International Courier User Fee	-	-	-	**$735**	**$735**
Field	-	-	-	735	735
FTE	-	-	-	3	3
User Fee FTE Total	**73**	-	**73**	**428**	**428**

The FDA Foods Program operates under the following legal authorities:

Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 321-399)
Federal Import Milk Act (21 U.S.C. 142-149)
Public Health Service Act (42 U.S.C. 201, *et seq.*)
Food Additives Amendment of 1958*
Color Additives Amendments of 1960
The Fair Packaging and Labeling Act (15 U.S.C. 1451-1461)
Safe Drinking Water Act (21 U.S.C. 349)
Saccharin Study and Labeling Act*
Infant Formula Act of 1980*
Drug Enforcement, Education, and Control Act of 1986*
Nutrition Labeling and Education Act of 1990*
Dietary Supplement Health and Education Act of 1994*
Food Quality Protection Act of 1996*
Federal Tea Tasters Repeal Act (42 U.S.C. 41)
Safe Drinking Water Act Amendments of 1996 (21 U.S.C. 349)
Food and Drug Administration Modernization Act of 1997*
Antimicrobial Regulation Technical Corrections Act of 1998*
Public Health Security and Bioterrorism Preparedness and Response Act of 2002*
Food Allergen Labeling and Consumer Protection Act of 2004*
Sanitary Food Transportation Act of 2005*
Dietary Supplement and Nonprescription Drug Consumer Protection Act (21 U.S.C.379aa-1)*
Food and Drug Administration Amendment Act of 2007*
Patient Protection and Affordable Care Act
FDA Food Safety Modernization Act (P.L. 111-353)

Allocation Method: Direct Federal/intramural; Contract

Program Description and Accomplishments

The Foods Program is a component of the FDA Foods and Veterinary Medicine (FVM) Program. The mission of the FVM Program is to protect and promote the health of humans and animals by ensuring the safety and proper labeling of the American food supply, animal feed and cosmetics, as well as the safety and effectiveness of animal drugs and devices. The FVM Program is comprised of the Center for Food Safety and Applied Nutrition (CFSAN), the Center for Veterinary Medicine (CVM), and the related field activities of the Office of Regulatory Affairs (ORA). The Office of Foods and Veterinary Medicine (OFVM) provides leadership and strategic direction to the FVM Program, including oversight of the wide range of responsibilities and activities of CFSAN and CVM.

*Authorities under this act do not appear in sequence in the U.S. Code. The authorities are codified as amended in scattered sections of 21 U.S.C.

The Foods Program consisting of CFSAN and ORA protects consumers by safeguarding the human food supply. Outbreaks of foodborne illness and contamination events have a substantial impact on public health – an estimated 48 million foodborne illnesses occur every year resulting in an estimated 128,000 hospitalizations and 3,000 deaths.[18] The average cost per case of foodborne illness is estimated at $1,626 and total more than $78 billion per year.[19]

Congress recognized the unique challenges faced by FDA in the area of food safety in the 21st century, and gave the Agency a modern legislative mandate to meet these challenges by enacting the FDA Food Safety Modernization Act of 2011 (FSMA). FSMA directs FDA to build a food safety system based on the public health principle of comprehensive prevention, an enhanced focus on risk-based resource allocation, and partnership across the public and private sectors to minimize hazards from farm to table.

The FDA *Foods and Veterinary Medicine Program Strategic Plan*[20] *(FVM Strategic Plan)* provides a framework for the implementation of FSMA and places high priority on the prevention of foodborne illness of unknown origins, as well as illness that can be specifically attributed to known sources.

To achieve the goals of the FVM Strategic Plan, the Foods Program focuses on securing high rates of compliance with science-based food safety and labeling standards by implementing integrated, prevention-oriented, and risk-based programs to protect the safety and security of foods and cosmetics and to ensure that food labels contain useful and reliable information.

The Foods Program executes its regulatory responsibilities in the following subprogram areas:

- Prioritizing Prevention
- Strengthening Surveillance
- Strengthening Enforcement
- Improving Response and Recovery
- Nutrition & Labeling Strategies for Better Health
- Reinventing Cosmetics Safety.

[18]Centers for Disease Control and Prevention. 2011. Estimates of Foodborne Illness in the United States. A comparable analysis cannot be made between CDC's 2011 estimates of foodborne illnesses and findings from earlier years due to a new methodology being used in 2011.

[19]Scharff, Robert L., "Economic Burden from Health Losses Due to Foodborne Illness in the United States," Journal of Food Protection, Volume 75, Number 1, January 2012, pp. 123-131(9).

[20] The FVM Strategic Plan can be found on the FDA web site at: http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofFoods/UCM273732.pdf

Prioritizing Prevention – Center Activities
Base Amount: $7,781,000 (All BA)

Public Health Focus and FDA Food Safety Strategy

The Foods Program's *Prioritizing Prevention* activities support the *FVM Strategic Plan* goals of establishing science-based preventive control standards across the farm-to-table continuum, as well as promoting the safe production of dietary supplements. FDA uses the results of regulatory science, product surveillance, and risk analysis to inform standard-setting activities and focus efforts to address both known and unknown sources of foodborne illness. Compliance, enforcement and response activities, such as inspections, administrative and judicial remedies, and food-related incident response, help FDA address issues that occur in the farm-to-table continuum and provide insight into areas where additional or expanded standards, controls, outreach, and education would improve food safety results.

Public Health Outcome

As part of the Foods Program, CFSAN addresses food safety risks at multiple points of the food supply chain through a combination of regulations, guidance, technical assistance, education, training and outreach, model codes for food service establishments such as restaurants, and consumer advice. CFSAN sets standards for protecting the food supply from tampering or other deliberate actions, and evaluates the safety of food additives, color additives, dietary supplements, and infant formula. In addition, CFSAN partners with agricultural and industry suppliers, distributors and marketers to improve their knowledge of regulations, guidance, hazards, and mitigation strategies. Below are examples of recent accomplishments in this subprogram that demonstrate progress towards the goals of the *FVM Strategic Plan*.

Issuance of Proposed Rules on Preventive Controls for Food Processing and Produce Safety: As part of FSMA implementation, FDA proposed two new food safety rules aimed at preventing and reducing foodborne illness in January 2013. The proposals were drafted following extensive outreach to industry, consumer communities, other government agencies, and the international community over the last two years. The first proposed rule would require makers of food to be sold in the U.S., whether produced at a foreign- or domestic-based facility, to have written plans that identify microbiological, chemical, physical, or radiological hazards that are reasonably likely to occur; specify the steps that will be put in place to prevent or minimize the hazards; identify monitoring procedures; record monitoring results; and specify what actions will be taken to correct problems that arise. The second rule proposes enforceable science and risk-based standards for the growing, harvesting, packing, and holding of fruits and vegetables on farms. These standards focus on agricultural water, soil amendments of biological origin, animal intrusion, worker health and hygiene, and equipment, tools, buildings, and sanitation. These two proposed rules are part of an integrated reform

effort that focuses on prevention and addresses the safety of foods produced domestically and imported.

Issuance of Interim Final Rule on Record Access Requirements for Food Firms: In February 2012, FDA issued an interim final rule amending its regulations on record-keeping by food firms to be consistent with FDA's access to records expanded by FSMA. The expanded records-access authority is expected to improve FDA's ability to respond to and contain safety problems with the human food supply. FDA also published an update to its guidance for industry, "Questions and Answers Regarding Establishment and Maintenance of Records (Edition 4)," to ensure the guidance is consistent with the new FSMA requirements.

Survey on the Occurrence of Foodborne Illness Risk Factors (2013-2022): In 2012, FDA continued to measure trends in the occurrence of foodborne illness risk factors--preparation practices and employee behaviors most commonly reported to the Centers for Disease Control and Prevention (CDC) as contributing factors to foodborne illness outbreaks at the retail level. FDA initiated this survey in 1998 and has created a new tool to better collect data for the Survey. The tool will be used over the next ten years and will provide FDA a solid foundation for developing a national retail food program model that can be used by Federal, state, local, and tribal agencies to improve identifying food safety risk and impact of industry food safety management systems.

Establishment of Alliance for FSMA Preventive Controls Training: In cooperation with the Illinois Institute of Technology's Institute for Food Safety and Health, FDA established the Food Safety Preventive Controls Alliance to develop training courses and materials on preventing contamination for both human and animal food during production. The materials to be developed by the alliance will help industry, particularly small- and medium-size companies, comply with the upcoming preventive controls requirements of the FDA Food Safety Modernization Act.

Preventing *Salmonella* – Egg Safety: *Salmonella* is the leading pathogen contributing to domestically acquired foodborne illness resulting in hospitalization and death. In its 2009 Egg Safety Rule, FDA established standards to protect consumers from *Salmonella* and save thousands of lives over the next few years. In FY 2012, FDA released a final Guidance for Industry on the production, storage, and transportation of shell eggs under the rule. The guidance document addresses questions regarding the requirements under the rule, including how to determine whether and when producers must comply with the requirements, *Salmonella* Enteritidis prevention measures, sampling and testing requirements, facility registration, and enforcement and compliance.

FSMA Food Facility Registration Guidance: FDA issued draft guidance on the Necessity of the Use of Food Categories in Food Facility Registrations and Updates to Food Categories, as provided by section 102 of FSMA. The Act requires both domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal

consumption in the U.S. to register with the FDA. Requiring the submission of food product category information as part of a facility's registration will help FDA to better protect the public by enabling quicker, more accurate, and more focused responses to an actual or potential bioterrorist incident or other food related emergency.

Import Safety – Systems Recognition: FDA is currently working on pilot activities to explore the use of systems recognition, previously termed "comparability," as one tool to help ensure the safety of imported foods and as a mechanism to establish a global coalition of regulatory partners. Systems recognition involves reviewing a foreign country's food safety regulatory system to determine if it provides a similar set of protections to that of FDA. Systems recognition will allow the agency to identify where leveraging of resources is most appropriate, allowing FDA to focus its resources on the highest risk commodity-country combinations. Systems recognition will allow the agency to identify where leveraging of resources is most appropriate, allowing FDA to focus its resources on the highest risk commodity-country combinations.

Following completion of FDA's first pilot with New Zealand, FDA and New Zealand's Ministry of Primary Industries signed a systems recognition cooperative arrangement on December 10, 2012. The agreement recognizes each other's food safety systems as comparable to each other, leading the way to a new level of regulatory cooperation to enhance food safety while facilitating trade between the two countries. This is the first time that FDA has recognized a foreign food safety system. A second pilot is currently underway with Canada under the U.S. Canada Regulatory Cooperation Council work plan, "Common Approach to Food Safety."

Import Safety – Developing Sustainable International Food Safety Training: FDA has partnered with the University of Maryland's Joint Institute for Food Safety and Nutrition (JIFSAN) to expand food safety training by developing strong sustainable partnerships with different regions of the world. The concept was piloted with the Bangladesh Shrimp and Fish Federation by establishing an Aquatic and Aquaculture Food Safety Training Center where a cadre of in-country trainers has conducted local programs for both the small aquaculture producers in rural areas and the larger companies. Based on the success of this endeavor, JIFSAN and FDA are using it as a model to establish other regional training centers for different food commodities.

In FY 2012, JIFSAN, CFSAN, and FDA's India Post established a partnership with the India Spice Board and the Coalition of India Industry-Food and Agriculture Center of Excellence to develop a program on Supply Chain Management for Spices and Botanical Ingredients. The first phase of the program, an in-country training program, was conducted in 2012; the second phase, a two-week internship program for small cadre of professionals who will become the in-country trainers is planned for early 2013. The initiative fosters and supports the implementation of modern food safety practices that protect the U.S. consumer from unsafe foods as required by FSMA and permits FDA to focus its future resources on other high priority food safety issues.

Prioritizing Prevention – Field Activities
Base Amount: $111,373,000 (All BA)

Public Health Focus and FDA Food Safety Strategy

ORA's top priorities for advancing public health and protecting consumers focus on:

- Prevention through outreach coordination and technical assistance to industry
- Internal and external training to increases expertise and encourages collaboration with external stakeholders
- Preventive controls throughout the food supply chain from production to delivery into the U.S. supply chain and ultimately to consumption by the public.

ORA achieves the overall FDA food safety strategy by focusing on preventing food safety problems rather than reacting to problems after they occur. These activities are part of the *FVM Strategic Plan* goals of establishing science-based preventive control standards and regulations across the farm-to-table continuum to protect the food and feed supply from contamination. This is accomplished by identifying the most significant foodborne contaminants and evaluating the effectiveness of existing controls for those contaminants.

Public Health Outcome

As part of the Foods Program, ORA participated in public outreach events that were attended by regulated industry, other government agencies, and foreign regulatory entities. Below are five examples of recent accomplishments in this subprogram that demonstrate progress towards the goals of the FVM *Strategic Plan*.

Compendium of Microbiological Protocols and Chemical Tests (COMPACT): The FDA Compendium of Microbiological Protocols and Chemical Tests is a compilation of analytical detection methods for foods designed to support the mission of FDA. In FY 2012, COMPACT, which is housed within the Electronic Laboratory Exchange Network (eLEXNET), released a new method – "Detection of Toxic Elements" – and made it available to the chemistry community. The eLEXNET is a seamless, integrated, secure network that allows multiple agencies (federal, state, and local health laboratories on a voluntary basis) engaged in food safety activities to compare, communicate, and coordinate findings of laboratory analyses. eLEXNET added three new labs in FY 2012. As of October 2012, 174 laboratories are participating in eLEXNET by submitting food-testing data. eLEXNET successfully completed the initial phase of a data sharing pilot with Canada Food Inspection Agency and Health Canada. FDA and Canada are collaborating so both countries can share food generated laboratory data associated with chemistry, microbiological, and radiological disciplines within their respective laboratory network systems.

Manufactured Foods Regulatory Program Standards (MFRPS): ORA provided funding through a cooperative agreement to 26 state food regulatory programs to support implementation of the Manufactured Food Regulatory Program Standards. At the end of FY 2012, a total of 41 programs in 40 states were enrolled in MFRPS. To provide support to these programs, ORA's Office of Partnerships conducted 44 visits with states to assist in their implementation of the standards. In addition, ORA's audit team conducted 11 state assessments to determine the states' progress in implementing MFRPS. ORA funded 31 state regulatory program laboratories and a laboratory association, the Association of Public Health Laboratories, under two cooperative agreements to provide support, best practices and training for laboratories to achieve International Organization for Standardization (ISO) accreditation. By working with these public health partners, FDA is establishing a fully integrated food safety system to prevent foodborne illness through the adoption and uniform application of model programs, like the Manufactured Food Regulatory Program Standards and other appropriate program standards.

Voluntary Retail Program Standards: In FY 2012, ORA provided funding through a cooperative agreement to 38 state, local, county, and city regulatory agencies to support implementation of the Voluntary Retail Program Standards. This cooperative agreement funding provides the means for these programs to build their capacity, capability and infrastructure to increase implementation of the retail standards and better protect public health.

Egg Safety Rule: In FY 2010, FDA began regulating firms under 21 CFR Part 118, "Production, Storage, and Transportation of Shell Eggs. Since then, ORA has conducted more than 550 inspections and collected more than150 shell egg samples including more than 2,000 environmental swabs. Twenty-two of the 150 samples and 51 individual environmental swabs were found positive for *Salmonella* Enteritidis (SE). ORA evaluates inspection and analytical findings and works with regulated industry to determine the appropriate corrective and regulatory actions such as issuance of warning letters, untitled letters, and voluntary recalls. ORA re-inspected firms with significant violations that warranted action by FDA to determine their compliance status. ORA also participated in industry outreach programs with the egg producing industry, providing education on compliance with the Egg Safety Rule.

In 2012, the Egg Safety Rule went into effect for smaller shell egg producers, those with between 3,000 and 49,999 laying hens. FDA has begun outreach efforts for this industry segment and began inspecting these smaller shell egg producers. Contracts were issued with eight state partners to conduct inspections of these facilities.

Integrated Food Safety System Cooperative Training Grants: Seven grantees involved in over 70 projects which covered all levels of regulatory responsibility, knowledge, skills, and abilities required for the technical specialist across multiple commodity areas. All of the grant projects contribute to the development and implementation of an

Integrated Food Safety System. The training and certification programs also support the Manufactured Food and Retail Food Regulatory Program Standards.

Performance Measures

The *Prioritizing Prevention* subprogram is supported by budget authority.

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
213301: Complete review and action on the safety evaluation of direct and indirect food and color additive petitions, within 360 days of receipt. (*Output)*	FY 2012: 92% Target: 80% (Target Exceeded)	80%	80%	Maintain
214101: Number of state, local, and tribal regulatory agencies in the U.S. and its Territories enrolled in the draft Voluntary National Retail Food Regulatory Program Standards. *(Outcome)*	FY 2012 :547 enrolled Target: 502 enrolled (Target Exceeded)	502 enrolled	587 enrolled	+85
212404: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: *Campylobacter* species. (*Outcome)*	CY 2010: 13.52 cases/100,000 CY 2010 Target: 12.4 cases/100,000 (Target Not Met)	11.9 cases/ 100,000	11.4 cases/ 100,000	- .5 cases/ 100,000
212405: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: Shiga toxin-producing *Escherichia coli* O157:H7. (*Outcome)*	CY 2010: 0.95 cases/100,000 CY 2010 Target: 1.15 cases/100,000 (Target Exceeded)	1.09 cases/ 100,000	1.00 cases/ 100,000	- .09 cases/ 100,000
212406: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: *Listeria monocytogenes*. (*Outcome)*	CY 2010: 0.27 cases/100,000 CY 2010 Target: 0.29 cases/100, (Target Exceeded)	.29 cases/ 100,000	0.27 cases/ 100,000	- .02 cases/ 100,000
212407: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: *Salmonella* species. (*Outcome)*	CY 2010: 17.55 cases/100,000 CY 2010 Target: 14.9 cases/100,000 (Target Not Met)	14.5 cases/ 100,000	13.9 cases/ 100,000	- .06 cases/ 100,000
212409: Reducing foodborne illness in the population. By December 31, 2013, decrease the rate of Salmonella Enteritidis (SE) illness in the population from 2.6 cases per 100,000 (2007-2009 baseline) to 2.1 cases per 100,000. (*Outcome*)	CY 2011: 3.0 cases/100,000 Target: 2.3 cases/100,000 (Target Not Met)	2.2 cases/ 100,000	2.0 cases/ 100,000	- .2 cases/ 100,000

Strengthening Surveillance – Center Activities
Base Amount: $135,274,000 (All BA)

Public Health Focus and FDA Food Safety Strategy

The Foods Program's *Strengthening Surveillance* activities support the *FVM Strategic Plan* goals to strengthen scientific leadership, capacity, and partnership to inform public health decision making, and to improve effectiveness and efficiency across the farm-to-table continuum. These activities inform the use of resources across all sub-programs, allowing FDA to target standard-setting, compliance, and response activities to best address both known and emerging food safety concerns.

Public Health Outcome

As part of the Foods Program, CFSAN conducts surveillance of domestic and imported products and evaluates commodity and hazard-specific risks to inform resource use in addressing known and unknown sources of foodborne illness. CFSAN also invests in advanced sciences and technologies to more efficiently address issues threatening the food supply. Below are examples of recent accomplishments in this subprogram that demonstrate progress towards the goals of the *FVM Strategic Plan*.

New Modeling Tool Increases Risk Ranking Capacity and Rapid Risk Assessment of Emerging Issues: FDA developed and released for public use on October 4, 2012, an innovative risk-assessment tool, FDA-iRISK. FDA-iRISK automates the time- and labor-intensive process of developing mathematical models to simulate risk and intervention in food-production chains. FDA-iRISK predicts the number of cases of illness prevented by various interventions applied against specific contaminants, in specific foods, at any or all points, from farm to table. Its automated features reduce the time and labor required for risk assessments, to provide faster access to information for regulatory decisions, such as those involving policies or resource allocation, and to give industry and others, including countries that export food to the U.S., a free, globally accessible, online mechanism for assessing how to improve food safety. FDA-iRISK is one of six finalists in the 2013 HHS Innovates Awards, and received Honorable Mention at an awards event held in March 2013 at which the "Secretary's Picks" were announced.

Produce Safety Risk Analysis: FDA conducted an experimental field trial of crop contamination to validate FDA's On-Farm Produce Quantitative Predictive Risk Assessment Model (QPRAM). QPRAM is a risk model that simulates transfer of the bacterium from the environment to produce and enables prediction of foodborne illnesses resulting from crop contamination. In estimating risk, the model takes into account a wide variety of farming practices, such as application of irrigation water, and environmental factors, such as topography and location of wild and domestic animals. The field trial was conducted in collaboration with the UC Davis Western Center for Food Safety. The information from this risk model will support FDA efforts to prevent foodborne illness resulting from consumption of contaminated produce.

Development of New Rapid Method for Identifying *Salmonella enterica*: CFSAN has developed a polymerase chain reaction (PCR) method for serotyping (identifying) *Salmonella enterica*; this new method can determine the type of 30 of the most clinically relevant serotypes with the potential for additional serotypes as needed. CFSAN developed and published a manuscript entitled, "Evaluation of a PCR-Based Method for Identification of *Salmonella enterica* Serotypes from Environmental Isolates and Various Food Matrices."

Development of Testing Protocol for Paralytic Shellfish Toxins: Federal waters off the New England Coast have been closed to shellfish harvesting since 1990 because of paralytic shellfish toxin (PST) outbreaks from algal blooms. FDA is responsible for advising the National Marine Fisheries Service (NMFS) about re-opening these regions to harvest, but FDA has not had the resources to investigate whether these areas are safe. FDA collaborated with NMFS, state shellfish authorities (Massachusetts, Rhode Island and Delaware), and industry to develop the On-Board Screening Dockside Testing Protocol, which requires pre-harvest screening of shellfish at sea using PST field kits. In 2011, this protocol was adopted into the National Shellfish Sanitation Program Model Ordinance as an approved marine biotoxin control strategy for use in federal waters. NMFS also provides an exempt permit for fishermen to harvest in affected areas as long as they follow the requirements of the protocol. The successful implementation and execution of the protocol enables industry to safely harvest an underutilized resource and provides FDA and NMFS with data to assess whether long-closed resources could be opened.

Listeria monocytogenes Market Basket Survey: In collaboration with other federal agencies, FDA completed Phase 1 of the *Listeria monocytogenes* Market Basket Survey, a comprehensive survey of ready-to-eat foods, to provide data on prevalence and levels of *Listeria monocytogenes* in food samples. *L. monocytogenes* imposes a particularly high mortality rate, and risk-assessment models have identified certain ready-to-eat foods that allow the growth of this pathogen, which can grow even during refrigerated storage, as higher-risk vehicles for transmission and subsequent listeriosis. The survey is providing vital data for risk models that compare listeriosis risk among ready-to-eat food categories. Phase II of the Market Basket Survey is underway to also examine characteristics of the foods, such as ingredients, formulations, and inhibitors.

Listeriosis Risk by Subpopulation: In collaboration with CDC, the FDA completed an analysis to determine the relative risk of listeriosis according to age, pregnancy, and ethnicity, based on CDC's FoodNet data. By quantifying the risk among these particularly high risk populations, the study is providing a better understanding of susceptibility for developing risk-assessment models and other disease-prevention efforts. Two papers co-authored by the two Agencies were published in *Clinical Infectious Diseases* in June 2012[21].

[21] Pouillot, R., Hoelzer, K., Jackson, K. A., Henao, O. L., & Silk, B. J. (2012). *Relative Risk of Listeriosis in Foodborne Diseases Active Surveillance Network (FoodNet) Sites According to Age, Pregnancy, and Ethnicity*. Retrieved from http://cid.oxfordjournals.org/content/54/suppl_5/S405.short

Egg Safety – Improved Detection Method: In response to a need for more rapid and sensitive screening protocols, FDA developed a highly sensitive microbiological detection method for *Salmonella* serovars Enteritidis and Heidelberg in eggs that reduces the time to obtain a confirmed isolate to five from nine days. This new method can be used to detect *Salmonella* contamination at levels as low as one cell of *Salmonella* in a 20 egg composited sample (*e.g.*, a one liter pool). The method is currently being drafted for inclusion in FDA's Bacteriological Analytical Manual, which presents the agency's preferred laboratory procedures for microbiological analyses of foods and cosmetics. This method supports implementation of FDA's Egg Safety Rule testing requirements for shell eggs and egg-production environments. For more information about this project, please see CFSAN's FDA-TRACK page.[22]

Strengthening Surveillance – Field Activities
Base Amount: $286,015,000 (All BA)

Public Health Focus and FDA Food Safety Strategy

To strengthen food defense and safety, surveillance and risk analysis, ORA conducts:

- Import prior notice and entry reviews
- Import field exams
- Import sample collections
- Domestic product reconciliation examinations
- Laboratory analyses including sample analysis, product testing, and methods development.

In the case of *Strengthening Surveillance*, ORA supports the overall FDA food safety strategy by:

- Establishing a structure to enhance risk-based decision making
- Developing metrics and goals for risk-based food safety priority setting
- Maintaining and strengthening mission-critical science capabilities.
- Improving centralized planning and performance measurement.
- Improving internal and external information sharing.

Silk, B. J., Date, K. A., Jackson, K. A., Pouillot, R., Holt, K. G., Graves, L. M., Ong, K. L., Hurd, S., Meyer, R., Marcus, R., Shiferaw, B., Norton, D. M., Medus, C., Zansky, S. M., Cronquist, A. B., Henao, O. L., Jones, T. F., Vugia, D. J., Farley, M. M., & Mahon, B. E. (2012). *Invasive Listeriosis in the Foodborne Diseases Active Surveillance Network (FoodNet), 2004–2009: Further Targeted Prevention Needed for Higher-Risk Groups*. Retrieved from http://cid.oxfordjournals.org/content/54/suppl_5/S396.short

[22] "Rapid Testing and Identification of *Salmonella* in Foods," http://www.accessdata.fda.gov/FDATrack/track-proj?program=cfsan&id=CFSAN-ORS-Rapid-Testing-and-Identification-of-Salmonella-in-Foods.

Public Health Outcome

As part of the Foods Program, ORA conducts surveillance of the nation's food supply to monitor and evaluate the food safety system. Below are examples of recent accomplishments in this subprogram that demonstrate progress towards the goals of the FVM *Strategic Plan*.

Mobile Laboratories: In FY 2012, ORA continued to use Chemistry and Microbiological Mobile Laboratories to support FDA's food defense initiatives and surveillance of import and domestic produce. The Mobile Laboratories are deployed to sites around the country to increase rapid surveillance of food samples. During the summer, the Chemistry Mobile Laboratories deployed to Davie, Florida where more than 140 samples of fresh, imported produce were analyzed for illegal pesticide residues, nine of which were found to contain illegal levels of pesticides. The Microbiological Mobile Lab deployed on three separate occasions where 2,185 imported and domestic samples (21,850 sub samples) that included soil, water, and fresh produce with a history of association to foodborne-outbreak illnesses, were analyzed for enterohemorrhagic *E. coli* and *Salmonella*. Eleven samples were confirmed positive for *Salmonella* and one was confirmed positive for Shiga toxin 2 (*stx*2). ORA took regulatory action and refused entry of the goods into the U.S. The mobile laboratories were able to quickly report the results to a central command using the Incident Command System (ICS) structure. ICS contacted the appropriate collecting districts where dissemination of results occurred. In September 2012, while deployed in Salinas, California, the mobile laboratory responded to an outbreak of Salmonellosis linked to mangoes from Mexico. The Microbiological Mobile Laboratories participated in a collaborative project with the Lawrence Livermore National Laboratory (LLNL) Biological Operation exercise. The LLNL exercise demonstrated the effective collaboration of two agencies from collection to analysis. An automated high-throughput molecular platform was put in place for the 2012 deployments to advance the mobile lab's technological capabilities. This new platform effectively increased the mobile lab's analytical throughput by 50 percent. In addition, an effort to enhance the self-contained nature of the laboratories, the microbiological mobile laboratory initiated preparation of media in-house and confirmation of any 'cannot rule out' sample for microbial adulteration. These additional procedures allowed the mobile lab to operate predominately independent of a fixed-site lab.

Environmental Sampling: In 2012, ORA and state regulatory partners under contract with FDA continued to use environmental sampling during domestic, high-risk food facility inspections to assess the environmental conditions in which products are manufactured. These environmental samples are critical in identifying areas of concern within the production environment that lead to product contamination. As a result of FDA's efforts, industry took many actions to recall or destroy products that were manufactured under such conditions.

Political Convention Food Defense Surveillance Assignments: In May 2012, FDA issued a pilot food defense assignment in preparation for elections which involved inspections and collections based on food defense risk assessment models. ORA utilized the Food Emergency Response Network (FERN) cooperative agreement laboratories to analyze multiple matrices and analytes of food defense concern. In total there were 143 radiological samples tested, 119 microbiology samples, and 154 chemistry samples analyzed. Some samples required multiple analyte detection and all results were successfully reported in a timely manner. Feedback from the pilot assignment was used to strengthen and update the surveillance performed during the Democratic and Republican national conventions. During those assignments there were a total of 32 chemistry, 34 microbiology, and 41 radiochemistry samples analyzed. Overall the FERN labs analyzed more than 500 samples. This assignment strengthened the communication and response of laboratories nationwide to respond to a chemical, microbiological or radiochemical threat to our food supply, in a politically tense and highly populous event situation.

Handheld Portable Analytical Tool Pilot Program: ORA continues to pilot and implement handheld analytical tools. The tools allow ORA investigators to perform analytical screening of a variety of FDA regulated products to detect high level contaminants such as toxic elements or to detect the presence of Active Pharmaceutical Ingredients (APIs) in dietary supplements when the products are imported into the United States.

In FY 2012, ORA implemented two different handheld devices at locations throughout the nation. One of the tools allows ORA investigators to screen imported dietary supplements for the presence of APIs. After screening more than 200 products, ORA investigators found 44 of the products screened positive for the presence of APIs. Full analyses performed by ORA laboratories found all 44 products contained Sibutramine. Sibutramine substantially increases blood pressure and pulse rate and may present a significant risk for people with a history of coronary artery disease, congestive heart failure, arrhythmias or stroke. ORA subjected the product to detention without physical examination and worked with U.S. Customs and Border Protection to seize these shipments, keeping these dangerous products out of the U.S. market.

Increased Residue Testing in Domestic Products: A European Union (EU) audit of the U.S. residue testing program in foods produced in U.S. and exported to EU has revealed areas where increased surveillance is beneficial. In response to the recommendations of the EU audit, ORA has increased its sampling and testing of target domestic foods such as milk, honey, shell eggs, select aquaculture species, and select farmed game meat for drug residues and chemical contaminants. Historically ORA has focused on import products as they tend to exhibit a higher violation rate than domestic products. However, the increased surveillance in domestic products in response to the EU audit recommendation provides a unique opportunity to take a snapshot of the chemical contaminant profile exhibited by select domestic products. The increased surveillance was started in FY 2012 and the activities carry over into FY 2013. The increased surveillance targets collection of approximately 800 distinct samples and

testing of each of these samples for a number of families of compounds including pesticides, persistent organic pollutants, metals, and mycotoxins. The activity produces thousands of analytical data points and gives an expansive overview of the residue testing profile of the targeted domestic products.

Development of Nanotechnology Capability: A Nanotechnology Core Facility involving ORA's Arkansas Regional Laboratory (ARL) and FDA's National Center of Toxicology Research (NCTR) became fully operational. This facility provides the necessary analytical tools and advanced imaging equipment to adequately characterize nanoscale materials within multiple FDA regulated product classes. Additionally, scientists at ARL have developed a method to screen dietary supplements for total silver content using a portable analytical tool. As silver is the most widely used nanomaterial in consumer products, this method has allowed ORA to expand its laboratory capabilities and strengthen its ability to make science-based regulatory decisions.

Field and Label Examinations: During FY 2012, ORA performed field and label examinations on more than 190,000 entry lines of food related products, refused more than 14,000 entry lines of volatile food related products, and issued 56 Import Bulletins increasing FDA's field surveillance over suspected food products. Those activities are performed to identify readily visible violations such as verification that the product labeling meets applicable compliance requirements or determining the presence of macro filth. Physically verifying that refused entry lines are exported or destroyed is imperative to the protection of public health, ensuring that refused products are prevented from reaching U.S. consumers.

Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT): ORA completed full national rollout of the Mission Accomplishment and Regulatory Compliance Services (MARCS), Imports Entry Review (ER), and Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting to all 16 import Districts. MARCS Imports ER is FDA's new application to make initial admissibility decisions, assign field work, and display the results of the PREDICT risk-based screening and database lookups. PREDICT is FDA's electronic screening tool for import operations that replaces the legacy screening tool Operational and Administrative System for Import Support (OASIS). PREDICT screens all lines of imported products electronically submitted to FDA via U.S. Customs and Border Protection (CBP) interface. PREDICT is designed to calculate a customized risk score for every line in an entry based on a number of factors including inherent risk of the product, data anomaly rules, data quality rules, and the compliance history of the firms manufacturing or shipping of the product. PREDICT also has automated database lookups link to data stored in Center's databases, such as a firm's registration, product listing, and approval status.

Division of Food Defense Targeting (DFDT): ORA's DFDT was established in response to regulations promulgated in conjunction with the Public Health Security and Bioterrorism Preparedness Act of 2002. DFDT carries out its role to protect U.S.

consumers from an intentional threat or actual terrorist attack on the U.S. food and feed supply. In FY 2012, ORA performed more than 81,000 prior notice reviews of food and feed. Every prior notice is electronically screened and targeted and all those identified as high risk receive an intensive security review.

Under the FSMA Smuggled Food/Feed Strategy, ORA collaborated with CBP and began targeting and conducting examinations of import shipments. The purpose of this collaboration was to identify and take enforcement action against those found to contain smuggled food/feed products. Smuggled food/feed presents a hazard to consumers and its entry erodes confidence in the safety of the food/feed supply. ORA and CBP conducted more than 1,000 examinations under this strategy and have taken action when appropriate, including the seizure of smuggled shrimp and peppers in FY 2012.

Performance Measures

The *Strengthening Surveillance* subprogram is supported by budget authority.

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
214306: The average number of working days to serotype priority pathogens in food (Screening Only) (*Output)*	FY2012: 6 working days Target: 6 working days (Target Met)	6 working days	4 working days	-2 working days
214207: The number of systems recognition assessments completed by participating countries to determine whether their level of food safety oversight is comparable to the level of food safety oversight of the FDA. (Outcome)	FY 2012: 6 assessments complete (Target Exceeded)	5	13	+8
214201: Number of prior notice import security reviews. *(Output)*	FY 2012: 81,888 Target: 80,000 (Target Exceeded)	80,000	80,000	Maintain
214202: Number of import food field exams. *(Output)*	FY 2012: 171,783 Target: 160,000 (Target Exceeded)	160,000	160,000	Maintain
214203: Number of Filer Evaluations. *(Output)*	FY 2012: 1,338 Target: 1,000 (Target Exceeded)	1,000	1,000	Maintain
214204: Number of examinations of FDA refused entries. *(Output)*	FY 2012: 10,229 Target: 7,000 (Target Exceeded)	7,000	7,000	Maintain

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
214206: Maintain accreditation for ORA labs. *(Outcome)*	FY 2012: 13 labs Target: 13 labs (Target Met)	13 labs	13 labs	Maintain

Strengthening Enforcement – Center Activities
Base Amount: $22,558,000 (All BA)

Public Health Focus and FDA Food Safety Strategy

The Foods Program's *Strengthening Enforcement* resources support the *FVM Strategic Plan* goal to achieve high rates of compliance with preventive controls and produce safety standards domestically and internationally. Inspections, field examples, and sample collection help FDA identify and address food safety risks throughout the production and handling stages of the global food supply chain, either in cooperation with industry or through compliance and administrative and judicial enforcement actions. These activities further provide information for FDA on areas where standards and outreach are working effectively to protect consumers and where additional efforts are required to strengthen the food safety system, including research and risk analysis on sources of foodborne contamination.

Public Health Outcome

As part of the Foods Program, CFSAN evaluates industry compliance with food standards and supports risk-based domestic and foreign safety inspections. CFSAN also leverages a variety of public health partners and regulatory mechanisms to verify the safety of food. Section 207 of FSMA provides FDA with the authority to detain food and prevent it from reaching the marketplace if there is reason to believe that the food is adulterated or misbranded. The food is held while FDA determines whether judicial enforcement action (e.g., seizure, injunction) is warranted. Below are examples of recent accomplishments in this subprogram that demonstrate progress towards the goals of the *FVM Strategic Plan*.

FSMA Enforcement Tools – Suspension of Facility Registration: Under FSMA, FDA received authorization to suspend a facility's registration if there is a determination that food manufactured, processed, packed, received, or held by a registered facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals. If the registration of a facility is suspended, food cannot be imported into or exported from the facility and food cannot be introduced into commerce from the facility.

On November 26, 2012, FDA issued an order suspending the facility registration for Sunland, Inc., Portales, New Mexico. Sunland is a producer of raw and roasted peanuts and peanut butter products. FDA took this step after CDC identified peanut

butter manufactured by Sunland as the likely source of a twenty-state outbreak of *Salmonella* Bredeney and FDA found *Salmonella* in multiple environmental and product samples. In addition, an FDA inspection conducted from September to October 2012 found numerous significant deviations from current Good Manufacturing Practice requirements (cGMPs) that could result in cross-contamination between raw peanuts and peanut products.

In December 2012, a U.S. District of New Mexico judge signed a consent decree imposing requirements on Sunland to keep potentially harmful products from entering the marketplace. The consent decree requires that Sunland comply with cGMP regulations and retain an independent sanitation expert to develop a sanitation control program that the company must then implement. In addition, for the peanut butter plant, the company must conduct environmental monitoring and testing to ensure that disease-causing organisms are not present in the facility or in its finished foods and must have comprehensive inspections conducted by an independent sanitation expert. The consent decree permits Sunland to receive, hold, and distribute raw, unshelled peanuts from its storage buildings because the raw, unshelled peanuts are bound for processing facilities that include a "kill step" to eliminate *Salmonella* and other pathogenic bacteria.
Based on the requirements of the consent decree, FDA determined that adequate grounds no longer existed to continue the suspension actions and reinstated Sunland's food facility registration. However, the company cannot process or distribute food from its peanut butter plant or peanut mill plant in Portales, New Mexico, until it has complied with the consent decree's requirements to the agency's satisfaction. Sunland must receive written authorization from the FDA prior to resuming operations at both its peanut butter and peanut mill plant. FDA continues work with Sunland to ensure that processing facilities include precautions to eliminate *Salmonella*.
Foreign Inspection Planning and Results: CFSAN developed a strategic plan to identify country/commodity combinations of interest based on identified risk factors and expert elicitation. The plan encompassed 26 commodity types in 54 countries and more than 3,700 potential foreign facilities. Processing of the plan included CFSAN communications with the embassy and foreign country competent authority in each identified country and FDA posts, when applicable. CFSAN then collected data and contacted each individual firm and transferred information on more than 1,700 firms to ORA to be targeted for inspection. ORA completed approximately 1,347 foreign inspections in 36 countries during FY 2012, exceeding the 1,200 goal set by FSMA.

CFSAN is evaluating the findings from these inspections and pursuing regulatory action when necessary against serious violations. Thus far, FDA added 21 firms to Import Alerts in order to subject the firms and their products to Detention without Physical Examination when offering their products for importation into the United States. FDA also issued Warning Letters to 21 firms and Untitled Letters to 15 firms.

Enhanced Models for Risk-based Selection of Domestic Inspection: Domestic facility risk categorization is part of a broader strategy to meet new inspection frequency

mandates under FSMA and ensure coverage of FDA's food facility inventory. In FY 2012, FDA developed a new framework for selecting domestic facilities for inspection based on factors of known safety risks, compliance history, and years since last inspection. As a result, FDA was able to categorize an estimated 80,000 domestic facilities as high-risk and non-high-risk. Additionally, FDA has developed a more structured method to prioritize sampling projects using a relative ranking tool as part of the decision-making process. Prioritizing surveillance, compliance and enforcement, and research projects for samples of finished product, ingredients, or environmental conditions helps to determine mechanisms for collection based on resource availability.

Dietary Supplement Enforcement Action: FDA recently took a variety of judicial enforcement actions to ensure industry compliance with dietary supplements safety standards. This included seizure action against products marketed with various therapeutic claims to treat serious diseases. The claims cause the products to be drugs, for which there is no FDA approval in place. FDA also worked with the Department of Justice to file injunctions against firms that did not comply with the dietary supplement current Good Manufacturing Practice (cGMP) requirements.

In addition to judicial enforcement actions, FDA issued 75 warning letters in 2012 related to failure to comply with the dietary supplement cGMP regulation. For example, in April 2012, FDA issued warning letters to ten manufacturers and distributors of dietary supplements containing dimethylamylamine (DMAA), for marketing products for which evidence of the safety of the product had not been submitted to FDA in accordance with the new dietary ingredient statutory notification requirement. As of April 2012, FDA had received 42 adverse event reports on products containing DMAA. Although the complaints did not establish that DMAA was the cause of the incidents, some of the reports included cardiac disorders, nervous system disorders, psychiatric disorders, and death. DMAA is known to narrow the blood vessels and arteries, which can elevate blood pressure and may lead to cardiovascular events ranging from shortness of breath and tightening in the chest to heart attack. Nine of the firms that received warning letters committed to ceasing formulating their products with the ingredient. Subsequent FDA inspections of three of the firms confirmed that they had discontinued use of DMAA in their products. FDA is following up with the remaining firms.

Strengthening Enforcement – Field Activities
Base Amount: $167,081,000 (BA: $ 150,859,000 / UF: $16,222,000)

Public Health Focus and FDA Food Safety Strategy

One of ORA's main food safety duties is to perform risk-based inspections of food producers and provide strong, effective, and efficient enforcement of FDA laws and regulations. The safety of the nation's food supply continues to be a top priority for regulatory agencies. ORA views state-based contracts, grants, and cooperative programs such as the Food Inspection Contracts as important mechanisms for

providing increased enforcement activities through an enhanced integrated food safety system.

In the case of *Strengthening Enforcement*, ORA achieves the overall FDA food safety strategy by:

- Conducting risk-based domestic and foreign food safety inspections
- Implementing new enforcement tools
- Improving mechanisms for assuring that imported foods meet preventive controls standards
- Improving collaboration with state, local, tribal and territorial officials and staff on inspection and compliance efforts.

Public Health Outcome

As part of the Foods Program, ORA conducts on-site inspections of regulated domestic and foreign food establishments and initiates enforcement actions to address violations of public health laws and regulations. Below are examples of recent accomplishments in this subprogram that demonstrate progress towards the goals of the FVM *Strategic Plan*.

Foreign Food Inspections: ORA performed 1,347 foreign food establishment inspections in 36 countries compared to 1,003 foreign food inspections conducted during the same period in FY 2011, a 34 percent increase. In FY 2012, an inspection of a foreign seafood processor revealed serious violations of the seafood Hazard Analysis and Critical Control Point (HACCP) regulation. The inspection noted that the firm's HACCP plan for tuna failed to list adequate monitoring procedures and frequencies to control histamine formation and *Clostridium botulinum* growth and potential toxin formation. As a result of this inspection, ORA took regulatory action and issued a Warning Letter to the firm.

FDA uses risk factors to target firms to inspect, focuses the on-site inspections in the most critical areas, and continues to leverage the work of our dedicated foreign inspection cadre and FDA inspection staff located at FDA's foreign offices, and our district-based investigators to enhance overall coverage of the foreign establishment inventory. An inspection of a foreign chocolate manufacturer revealed that the firm had shipped 216 cases of chocolate bars to the U.S. from a lot that tested positive for *Salmonella risen*. As a result of this finding, the U.S. distributor was visited and the entire shipment was placed on hold therefore preventing the potentially contaminated chocolate bars from reaching the U.S. consumer.

Food Inspection Contracts: ORA awarded food inspection contracts to state agencies and territories. These contracts enhance an integrated food safety system by providing states and territories with funding to perform basic Good Manufacturing Practices (GMP) inspections as well as inspections in high risk industries such as juice and

seafood under HACCP and low acid canned foods and acidified foods.

The 41 state programs currently enrolled in MFRPS conduct 96 percent of all GMP inspections performed under FDA contract. ORA created the Manufactured Food Regulatory Program Alliance through a cooperative agreement to provide additional resources, training, and support to programs that are implementing the standards. In FY 2012, FDA issued contracts with eight state programs to complete inspections under the Egg Safety Rule. In FY 2012, ORA saw 56 jurisdictions newly enroll in the voluntary retail program standards. Currently, 534 jurisdictions are enrolled.

Enforcement and Recall Activities: In FY 2012, there were nine injunctions and five seizures against food and dietary supplement processors and manufacturers. These enforcement actions protect consumer safety by assuring that processors and manufacturers comply with laws and violative food and dietary supplement products are not distributed into commerce.

FDA classified 317 Class I, 306 Class II, and 75 Class III recalls of food products. ORA monitors recalls of food products and ensures the effectiveness of the firm's recall to remove the defective product from commerce.

Office of Criminal Investigations (OCI): During FY 2012, ORA's OCI made 37 arrests and secured 32 convictions with fines, restitutions, and other monetary penalties in excess of $9.8 million. Representative cases include:

Adulterated cheese- In April of 2012, four individuals from Mexico, Illinois, and Wisconsin were indicted on charges for conspiring to ship and distribute more than 110,000 pounds of Mexican cheese throughout the U.S. after FDA detained and ordered the cheese to be held for inspection. The cheese was later determined to be adulterated with *Salmonella*, *E. coli*, and other illness-causing bacteria. The four defendants scraped off mold and fungus from cheese returned by dissatisfied customers, re-sold it, and later lied to an FDA inspector to cover up the illegal redistribution/sales of the adulterated cheese. The four defendants owned or worked for companies responsible for importing and manufacturing the cheese.

Prickly pear- In California a group of import brokers were engaged in a scheme to defraud FDA. They helped customers import goods barred by FDA, including produce infected by *Salmonella* Agona, a life-threatening infectious bacteria. On one occasion, after a shipment of nopal cactus (also known as prickly pear) tested positive for *Salmonella*, coconspirators illegally changed the description of the nopal cactus' grower for subsequent shipments, for the purpose of evading future FDA inspections. Similarly, other offenders conspired to import Mexican snack foods that were mislabeled and adulterated with a prohibited dye.

OCI's investigation into adulterated and unsafe foods protects the public by ensuring compliance with FDA procedures designed to keep the public safe from food-borne

illnesses. The purchase of contaminated and adulterated products poses significant risks to the public health and has the potential to severely sicken consumers, and having effective criminal enforcement of the FD&C Act sends the message to the food industry that they must take their obligations seriously.

Performance Measures

The *Strengthening Enforcement* subprogram is supported by budget authority, Food Recall user fee, and Food Reinspection user fee.

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
214205: As required by the FSMA Legislation, cover 100% of the High Risk domestic inventory (approximately 22,000 firms) every three years. *(Output)*	FY 2012: 85%* (Historical Actual)	NA	33%	NA

*The assumed FY 2011 target would have been 33%, and the assumed FY 2012 target would have been 67%, although the goal was only officially established this year with the FY 2013 target. Because FDA is required to cover 100% of the firms every three years, the target for the first year of the new cycle, in this case FY 2014, returns to 33%.

Improving Response and Recovery – Center Activities
Base Amount: $4,225,000 (BA: $3,761,000 / UF: $464,000)

Public Health Focus and FDA Food Safety Strategy

The Foods Program's *Improving Response and Recovery* activities support the *FVM Strategic Plan* goal of improving detection of and response to foodborne outbreaks and contamination incidents. FDA detects and contains illness outbreaks and contamination incidents, and analyzes such events to improve the effectiveness of the food safety system. FDA also works closely with public health agencies and regulatory partners at Federal, State, local, tribal and territorial levels to improve data collection, analysis, sharing, and communication both within government and with industry and consumer stakeholders.

Public Health Outcome

As part of the Foods Program, CFSAN develops and adopts innovative technologies and processes, including enhanced implementation of the Reportable Food Registry, that enable improved response to foodborne outbreaks and contamination. CFSAN also conducts risk communications related to outbreaks and contamination incidents and uses data from incident investigations to inform prevention efforts. Below are examples of recent accomplishments in this subprogram that demonstrate progress towards the goals of the FVM Strategic Plan.

Global Pathogen and Outbreak Detection Using Next-Generation Sequencing: CFSAN has partnered with food safety agencies and institutions from around the world to define and develop solutions to questions and challenges surrounding the deployment of next-generation DNA sequencing tools for public health and disease outbreak detection. In FY 2012, CFSAN hosted two international meetings with 24 different government agencies across 12 countries to establish a globally endorsed framework for using whole genome sequencing as the basis for global pathogen identification and disease detection. This effort will allow FDA to improve its foodborne illness outbreak response capability by creating stronger databases for outbreak source tracking and traceability of foodborne pathogens.

Public-Private Partnership to Spearhead Development of 100,000 Pathogen Genome Public Database: CFSAN recently partnered with the National Center for Biotechnology Information, the University of California Davis, BGI America, and Agilent Technologies, Inc. to launch a five-year effort to more quickly identify the source contamination in foodborne illness outbreaks and to keep additional contaminated product from entering the market. "The 100,000 Genome Project" will entail the genome sequencing of approximately 100,000 subtypes of common pathogens such as *Salmonella*, *Listeria*, and *Escherichia coli.* The information from this project will be made available in a free public database. This project will allow quicker identification of foodborne pathogens, and improved ability to pinpoint the sources of food contamination and to keep additional contaminated product from entering the market. Founders of the initiative, including several CFSAN microbiologists, were honored as recipients of the "Secretary's Pick" for the 2012 Health and Human Services Innovates Award, presented by Secretary Sebelius at a special innovation awards event held in September 2012.

Second Annual Report for the Reportable Food Registry (RFR): The Reportable Food Registry (RFR) enables mandatory electronic reporting of adulterated and potentially harmful foods by industry, and speeds the identification and investigation of potential health hazards in food. In April 2012, FDA published the second "Reportable Food Registry (RFR) Annual Report."[23] The report demonstrates the success of the program in improving the ability of the FDA to target its activities based on product risk and trace reportable foods throughout the farm-to-table continuum based on early warnings. The report also provides valuable insight on specific hazards affecting the food supply. The 225 primary reports for the second year involved products in 22 commodity categories. Salmonella accounted for 38.2 percent of hazards; undeclared allergens accounted for 33.3 percent; and Listeria monocytogenes accounted for 17.8 percent. In June 2012, FDA launched an updated RFR Rational Questionnaire to incorporate additional information that meets FSMA requirements to improve FDA's ability to track patterns of adulteration in human food to target its inspection and response resources.

[23] "The Reportable Food Registry: A New Approach to Targeting Inspection Resources and Identifying Patterns of Adulteration." Retrieved from http://www.fda.gov/Food/FoodSafety/FoodSafetyPrograms/RFR/ucm200958.htm

Seafood Response and Recovery Efforts: FDA has responded to numerous threats and outbreaks related to seafood. From 2008 to 2012 FDA responded to multiple diarrhetic shellfish poisoning (DSP) incidents caused by unprecedented blooms of a phytoplankton species in coastal waters of Texas and Washington State. The blooms produce toxins that cause DSP and have significant human health and economic impacts worldwide. CFSAN responded by providing subject matter expertise who provided technical expertise and training to state public health counterparts in Texas and Washington state.

FDA has also responded to outbreaks of ciguatera fish poisoning (CFP), which is caused by consumption of fish contaminated with polyether neurotoxins called ciguatoxins. CFP is one of the leading causes of finfish-related illness in the world, with severe acute and chronic effects. During 2012, CFSAN provided analytical assistance for CFP outbreak investigations to public health agencies in Texas, Florida, and Puerto Rico. In April 2012, CFSAN also offered a hands-on CFP training workshop for federal and state public health counterparts.

Improving Response and Recovery – Field Activities
Base Amount: $49,327,000 (All BA)

Public Health Focus and FDA Food Safety Strategy

The globalization of the U.S. food supply, rapid and widespread distribution of food, and changes in consumer expectations create the need for a framework for food protection. Protecting the U.S. food supply requires an integrated approach for recognizing, investigating, and responding to foodborne illnesses.

ORA devotes resources to the prompt and efficient response to foodborne outbreaks and events. ORA also identifies and develops new investigational resources, tools, and training programs while establishing an infrastructure that support continued effective and efficient response. As FDA continues to move forward in meeting national food defense goals, it relies on states and local health agencies to assist in improving preparedness and response activities. Grant and cooperative agreement funds allow states and counties to increase efficiency in the areas of response, prevention, and intervention in addition to allowing for a larger pool of resources nationwide to strengthen food defense and mitigate safety issues.

In the case of *Improving Response and Recovery*, ORA achieves the overall FDA food safety strategy by exploring and adopting innovative technologies and processes to detect and investigate outbreaks and contamination incidents, and by using effective risk communications in response to such events. ORA responds to issues that occur across Farm-to-Table continuum based on analyses of outbreaks and lessons learned from earlier responses.

Public Health Outcome

ORA partners with public and private entities to leverage data sharing and personnel. Examples of these FDA outreach partnerships include state contracts, FERN laboratories, rapid response and state lab cooperative agreements, Partnership for Food

Protection, Food Protection Task Force grants, and 50 state meetings. In FY 2012 FDA funded the expansion of the Rapid Response Teams (RRTs) cooperative agreement with the inclusion of new states into the program.

In FY 2012 ORA provided funding to 36 state, local, tribal and territorial partners to support capacity building in the areas of recalls and inspections in support of Section 210 of FSMA. This work enables federal and state partners to improve their systems to quickly and effectively stop an outbreak and mitigate the concern. ORA supported the newly formed Coordinated Outbreak Response and Evaluation (CORE) organization, which was formed specifically to improve FDA's response to foodborne illness outbreaks. ORA, CFSAN, and CORE worked collaboratively on multiple outbreaks resulting in improved communications throughout FDA and with federal and state agencies. In FY 2012, a multi-agency Incident Management Group was formed comprised of FDA, the Centers for Disease Control and Prevention (CDC), and numerous state Health Agencies to investigate a nationwide *Salmonella* outbreak. The group was able to identify a specific foreign supplier of ground tuna suspected to be the source of the outbreak and remove the contaminated product from commerce. FDA worked with the foreign competent authority that subsequently closed the firm following a violative inspection.

The globalization of the U.S. food supply, rapid and widespread distribution of food, and changes in consumer expectations create the need for a framework for food protection. Protecting the U.S. food supply requires an integrated approach for recognizing, investigating, and responding to foodborne illnesses. In FY 2012, ORA worked with the states to establish new and develop further existing Rapid Response Teams (RRTs), comprised of both ORA and state inspectors. An additional ten RRTs were funded by the end of FY 2012 which resulted in a total of 19 RRTs.

ORA scientists developed collaborations with the states of Massachusetts, New Hampshire, and Vermont to extend and enhance the much needed capability of surveillance testing for radionuclides in food samples. The Federal-State collaboration involved the collection and analyses of fish samples from these states for the presence of radionuclides. The study provided a baseline measurement for current and future comparisons and addressed the public's health concern of radionuclide contamination.

Japan Earthquake and Tsunami: As part of FDA's response to the March 2011 Japan earthquake and tsunami that caused explosions at Fukushima nuclear facilities, FDA issued Import Alert# 99-33 to identify products that were banned by the Japanese

government. FDA also continued its increased surveillance of Japanese food and drug products under Import Bulletin 99-B38, and provided a network of coverage to ensure no radiation-contaminated product reached U.S. consumers. Through the middle of July 2012, ORA field offices conducted more than 7,000 examinations and ORA field laboratories analyzed more than 200 samples, with no objectionable findings. At that point in time it was determined this increased level of surveillance was no longer warranted and coverage of products reverted back to routine surveillance levels.

Listeria monocytogenes Outbreak: In FY 2012, a U.S. foodborne outbreak of *Listeria monocytogenes* was associated with cantaloupes. The outbreak sickened many people causing hospitalizations and deaths. As part of FDA's response, ORA investigators, in collaboration with FDA's Coordinated Outbreak Response and Evaluation Network, CFSAN, CDC, and state and local health agency staff, conducted an investigation at the implicated farm and collected samples of cantaloupes as well as environmental samples at areas of interest. ORA field laboratory analysis confirmed the presence of *L. monocytogenes* in the cantaloupes, and FDA was able to work with the domestic farm to issue a recall. Throughout the event, FDA and CDC collaborated and updated the events on web postings, providing consumer guidance on proper cleaning and sanitizing of refrigerators, food contact surfaces, and utensils. These activities have improved FDA's response to outbreaks. Prevention of outbreaks substantially improves the safety of food consumed by the public.

Laboratory Information Management System (LIMS): ORA is in the process of developing the Laboratory Information Management System that seeks to improve the capability of the FDA labs to provide the necessary evidence, tracking, and effective sample management throughout the analytical process. The LIMS is a nation-wide automated system that corrects a major shortcoming in the methods that ORA Laboratories process and report on assigned samples. LIMS is capable of electronically capturing, storing, and reporting data pertaining to laboratory operations. LIMS provides the information technology enhancements to increase performance and the efficiency of the ORA laboratory operations.

Import Trade Auxiliary Communications System (ITACS): ORA made the Import Trade Auxiliary Communications System available to the public. ITACS is an internet portal that provides the import community the ability to check the status of individual entries, to submit entry documentation, and to provide the availability of information for targeted shipments. ITACS enhances the entry review process by providing the import community with the ability to provide information electronically and improve communication with ORA field offices.

Performance Measures

The *Improving Response and Recovery* subprogram is supported by budget authority and the Food and Feed Recall user fee.

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
214305: Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week). *(Outcome)*	FY 2012: 2,500 rad & 2,100 chem Target: 2,500 rad & 2,100 chem (Target Met)	2,500 rad & 2,100 chem	2,500 rad & 2,100 chem	Maintain

Nutrition & Labeling Strategies for Better Health – Center Activities
Base Amount: $17,093,000 (All BA)

Public Health Focus and FDA Food Safety Strategy

The Foods Program's *Nutrition & Labeling* activities support the *FVM Strategic Plan* goals of providing accurate and useful nutritional information and encouraging food product reformulation. Excess intake of calories, dietary fat, and sodium contribute significantly to rising rates of chronic disease, including hypertension, heart disease, stroke, diabetes, and obesity. CDC data indicate that more than 30 percent of the American adult population, approximately, 60 million people,[24] is obese and that 17 percent of children and adolescents aged 2 to19 years are obese.[25] FDA investments enable consumers to choose a healthier diet and reduce the risk of chronic disease and obesity.

Public Health Outcome

As part of the Foods Program, CFSAN promotes healthful dietary practices through truthful and informative labeling on food items, menus, and vending machines. CFSAN works with industry and consumer groups to determine the best methods for conveying nutrition information and increasing awareness around these initiatives. In support of HHS and Administration priorities to improve childhood nutrition, CFSAN works to ensure that nutrition labels specifically targeted to parents and children are clear and informative. CFSAN also uses scientific leadership and influence and, when

[24] "Overweight and Obesity – Adult Obesity Facts," Centers for Disease Control and Prevention. Retrieved from http://www.cdc.gov/obesity/data/adult.html
[25] "Overweight and Obesity – Data and Statistics," Centers for Disease Control and Prevention. Retrieved from http://www.cdc.gov/obesity/childhood/data.html

appropriate, regulatory tools to foster the development of healthier food products. Below are examples of recent accomplishments in this subprogram that demonstrate progress towards the goals of the *FVM Strategic Plan*.

Reduction of Trans Fat Blood Levels in Consumers due to Labeling Requirements: FDA completed an updated intake estimate for *trans* fat, which showed that consumption of *trans* fat has decreased significantly from 2003 to 2010. The reduction coincides with FDA's requirement for manufacturers to declare *trans* fat levels on the Nutrition Facts panel along with saturated fat and dietary cholesterol, which became effective on January 1, 2006, and resulted in product reformulations to reduce or eliminate *trans* fat. Consistent with this FDA study, a recent study by the CDC demonstrated that the amount of *trans* fat (i.e., *trans* fatty acids) present in American consumers bloodstreams decreased by 58 percent from 2000 to 2008. Scientific evidence shows that consumption of saturated fat, *trans* fat, and dietary cholesterol raises low-density lipoprotein (LDL or "bad") cholesterol levels that increase the risk of coronary heart disease.

Gluten-Free Labeling: In February 2013, FDA submitted to OMB for review a final rule that defines "gluten-free" for labeling food products, including dietary supplements, to better protect consumers who are gluten sensitive or who suffer from celiac disease.

Education and Outreach to Promote Healthy Diets: Partnering with the Joint Institute for Food Safety and Applied Nutrition, FDA co-sponsored a Dietetics and Nutrition Webinar in March 2012, for practitioners and educators in dietetics, as well as students, interns, and fellows who are preparing for professions in nutrition, food science and food technology. The information provided assists practitioners and educators in understanding FDA nutrition activities, such as food labeling, updating the Nutrition Facts panel, front of pack labeling, and dietary guidance statements. The webinar was designed to be interactive and the presentations were videotaped and made available for up to one year. This is an example of FDA's efforts to communicate valuable nutrition information to a wide audience in a resource efficient manner.

Revocation of Standard Identify for Artificially Sweetened Jelly, Preserves, and Jams: In December 2012, FDA published a proposal to revoke the standards of identity for artificially sweetened jelly, preserves, and jams. The action was taken primarily in response to a citizen petition submitted by the International Jelly and Preserve Association. FDA tentatively concluded that these standards are both obsolete and unnecessary in light of our regulations for foods named by use of a nutrient content claim and a standardized term. FDA also tentatively believes that this change will promote honesty and fair dealing in the interest of consumers.

Standard of Identity for Honey: In October 2012, FDA denied a Citizen Petition requesting the adoption of a standard identify for honey. The American Beekeepers Association and several American honey trade associations requested that FDA to adopt a standard of identity for honey. The petitioners maintained that a standard of

identity would inform consumers what “honey” means, combat economic adulteration, and promote honesty and fair dealing within the food trade. However, as FDA stated in the denial letter, the petitioners’ goals can be achieved using existing FDA authorities and therefore, a standard of identity for honey is not needed. FDA is also working on guidance about the composition and labeling of honey.

Performance Measures

The *Nutrition & Labeling* subprogram is supported by budget authority.

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
212408: The percentage of American consumers who recognize dietary steps that they can take to reduce their risk of chronic disease. (Outcome)	NA	NA	Set Baseline	NA

Reinventing Cosmetics Safety – Center Activities
Base Amount: $7,781,000 (All BA)

Public Health Focus

FDA’s *Reinventing Cosmetics Safety* activities support the Agency’s goal of monitoring the safety of cosmetics marketed in the United States, whether manufactured domestically or imported. The cosmetic industry is changing rapidly as manufacturing becomes more global, as technologies become increasingly sophisticated, and as cosmetic ingredients become more complex. Products containing ingredients produced through nanotechnology and “cosmeceuticals,” the industry-named category of products that purports to straddle the line between cosmetics and drugs, both present particular scientific and public health challenges.

Public Health Outcome

As part of the Foods Program, CFSAN provides direction to industry through guidance and outreach, and conducts compliance and enforcement activities, product surveys, sample analyses, and laboratory investigations in order to prevent harm to consumers from unsafe cosmetics or ingredients. CFSAN also evaluates adverse event reports and consumer complaints, and maintains systems for voluntary cosmetic product registration. Below are examples of recent accomplishments in this subprogram that demonstrate progress towards the goals of the *FVM Strategic Plan*.

Guidance and Outreach on the Safety of Nanomaterials in Cosmetic Products: Nanotechnology is an area of emerging science that is increasingly being applied to the development and production of cosmetics. Nanoparticles used in cosmetic ingredients may result in products with different chemical or physical properties that may pose different safety issues.

In April 2012, FDA issued draft guidance on the safety assessment of nanomaterials when used in cosmetic products. The document advises industry that the legal requirements for cosmetics manufactured using nanomaterials are the same as those for any other cosmetics. The guidance also states that standard safety tests may need to be modified or new methods developed in order to conduct safety assessments for cosmetic products containing nanomaterials, and encourages manufacturers to consult with the agency before taking their products to market. Such consultation helps FDA experts address questions related to the safety or other attributes of nanotechnology products, or answer questions about their regulatory status.

Consumer Education and Outreach to Improve Cosmetics Adverse Event Reporting: As cosmetics are not subject to FDA approval before they are made available on the market, consumers are one of the most important sources of information for FDA in identifying potential safety problems. In order to increase consumer awareness of the importance of reporting adverse events for cosmetic products, FDA recently developed a variety of data collection tools and consumer-friendly information resources. Key project accomplishments include development of a web-based survey that measured baseline consumer awareness levels, a Consumer Update entitled, “Bad Reaction to Cosmetics? Tell FDA,” that was widely distributed through media outlets, a corresponding video, an *FDA Basics* webinar that included a live question and answer session, and the distribution of printed materials at four public health conferences.

International Cooperation on Cosmetics Regulation (ICCR) Meeting: In July 2012, FDA hosted the sixth meeting of the ICCR, a quadrilateral effort among the cosmetics regulatory bodies of the United States, Canada, the European Union and Japan. Topics included the characterization and safety assessment of nanomaterials, alternative (non-animal) test method validation, trace level contaminants (lead and 1,4-dioxane), standard operating procedures, endocrine disruptors, in-silico methods for cosmetic ingredient safety assessments, and future expansion of ICCR. In preparation for this meeting, FDA held a public meeting to allow for transparency of process and presentation of perspectives from consumer advocates and other stakeholders. The purpose of the multilateral framework of ICCR is to maintain the highest level of global consumer protection, while minimizing barriers to international trade.

Tattoo Ink Safety: CFSAN alerted tattoo artists, ink and pigment manufacturers, public health officials, health care professionals, and consumers that some tattoo inks, and pigments used to color them, can be contaminated with various pathogens. Contaminated products may place consumers at risk of infections, such as impetigo, cellulitis, herpes simplex, tetanus, staph, fungal infections, syphilis, leprosy and viral

warts. Serious infections related to *Mycobacterium chelonae* have been reported in at least five states since 2011, and are sometimes mistaken for allergic reactions, complicating treatment of the infection.

Currently there is no specific FDA regulatory requirement that tattoo inks be sterile, however, companies and individuals who manufacture or market cosmetics, including tattoo inks, have a legal responsibility to ensure the safety of their products. Manufacturers are not required to reveal their ingredients, which may include iron oxides (rust), metal salts, plastics. Homemade or traditional tattoo inks may also be made from pen ink, soot, dirt, blood, or other ingredients. FDA has advised consumers to request the use of sterile water to dilute inks when receiving a tattoo, so that bacteria are not introduced during the dilution process.

Reinventing Cosmetics Safety – Field Activities
Base Amount: $3,253,000 (All BA)

Public Health Focus

ORA provides coverage of the rapidly expanding import and domestic cosmetic programs by conducting inspections and sample analyses on products in order to prevent unsafe cosmetics or ingredients from reaching consumers in the U.S..

Public Health Outcome

As part of the Foods Program, ORA provides coverage of the rapidly expanding import and domestic cosmetic programs by conducting inspections and sample analyses on products in order to prevent unsafe cosmetics or ingredients from reaching consumers in the U.S. Below are examples of recent accomplishments in this subprogram that demonstrate progress towards the goals of the *FVM Strategic Plan*.

Cosmetic Accomplishments*:* ORA issued more than 55 notices identifying modifications to cosmetics-related Import Alerts encompassing violations related to microbiological contamination and non-permitted or undeclared color additives. An example is Import Alert # 53-15 published on November 7,2012 “Detention Without Physical Examination of Eye Area Cosmetics Containing Kohl, Kajal, or Surma”, These actions were a result of ORA import surveillance collections and testing of regulated cosmetic products at the time they were offered for import into the United States. These notices serve to provide increased coverage at the border to assure these products are not available to the U.S. consumer.

CDC notified FDA that *Mycobacterium Chelonae* was identified from skin biopsies samples that were taken from rashes on tattooed areas of people’s bodies. The outbreak was far reaching with 26 confirmed cases in five states. ORA investigators performed numerous inspections of tattoo establishments, gathering information, and collecting tattoo ink samples as well as environmental samples in the establishments.

Laboratories are analyzing the samples to help identify the source of the contamination and the investigation is ongoing.

Performance Measures

The *Reinventing Cosmetics Safety* subprogram is supported by budget authority and the Cosmetics user fee.

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
214208: Number of American consumers who are aware of FDA's Adverse Event Reporting System for Cosmetics. (Outcome)	NA	Set baseline	+10% over baseline	NA

Information Technology Investments – Foods Program Activities (Base Amount displayed as a non-add item: $117,362,345)

Public Health Focus and FDA Food Safety Strategy

FDA's information technology (IT) investments provide cross-cutting support across all *FVM Strategic Plan* goals. IT investments allow FDA to capitalize on pre- and post-market data, scientific research, and current event information in order to better monitor and evaluate the safety of the food supply from farm to table. IT tools, systems, and infrastructure allow FDA to improve and expedite the identification of threats to the public health, and ultimately reduce the incidence of foodborne illness outbreaks.

Public Health Outcome and Accomplishments

FDA promotes improved public health through agile technology solutions designed to provide the right data at the right time to right people in support of risk-based decision making. This approach results in the prevention and mitigation of potentially harmful outbreaks of foodborne illnesses. Ongoing efforts to harmonize quality data lead to the timely adoption of science-based regulations that protect our food and feed supply, improve assurance that imported foods and feeds meet preventive controls standards, and improve collaboration with Federal, State, local, tribal, territorial and international stakeholders on inspection, compliance, and response efforts.

Center:

CFSAN invests in modern information technology and scientific computing tools and resources necessary to achieve regulatory, research, and administrative mission goals,

including implementation of the Food Safety Modernization Act. Below are examples of recent accomplishments enabled by CFSAN IT investments that demonstrate progress towards the goals of the *FVM Strategic Plan*.

Launch of New Risk Assessment Website: In 2012, FDA launched a new risk assessment website[26] to provide public information on assessing risks and completed, current, and planned FDA projects, and to request public input. The website responds to the Institute of Medicine's call for greater visibility and transparency and informs the public that FDA not only responds to emergencies, but also acts to prevent such events.

New Electronic Option to Expedite Registration for Low-Acid Canned Food and Acidified Food (LACF/AF): In June 2012, FDA implemented electronic registration capability for foreign and domestic commercial LACF/AF facilities. Previously, paper forms were transcribed into the database and source documents manually filed in the event of litigation and to confirm information in the database. The new electronic option significantly expedites registration of facilities for manufacturers, processors, and packers of LACF/AF. Also, the new capability improves data quality of firm information to better inform FDA decision-making.

New E-application System for Certificates of Free Sale: FDA implemented an automated system for companies exporting food from the U.S. to file electronically for Certificates of Free Sale in June 2012. Such certificates are often requested by international customers or governments to verify that the products being exported meet certain standards. The FDA Unified Registration and Listing Systems (FURLS) Certificate Application Process (CAP)27 allows exporters of conventional foods, including seafood, to apply online for a Certificate of Free Sale, reducing the amount of time required for the FDA to process requests and issue certificates.

Automated Research Tracking System: CFSAN led the expansion of the Center's Component Automated Research Tracking System (CARTS) across the entire FDA Foods and Veterinary Medicine Program to create a new, modern, automated tool that consolidates and standardizes management of all FVM scientific research portfolio projects. CARTS provides increased monitoring, including review and management of intramural and extramural projects, for foods, cosmetics, dietary supplements, safety, security, and nutrition research in CFSAN, CVM, and ORA. As an FDA enterprise system, CARTS also enhances the FDA's strategic planning capabilities and satisfies new FSMA requirements, including biennial research reports for Congress.

FSMA Biennial Registration of Food Facilities: FSMA amended section 415 of the F.D&C Act, which requires domestic and foreign facilities that manufacture, process,

[26] "Risk Assessment /Safety Assessment," Retrieved from http://www.fda.gov/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/default.htm.

[27] "FDA Industry Systems," Retrieved from http://www.access.fda.gov.

pack or hold food for human or animal consumption in the U.S. to register with FDA and renew their registrations with FDA every other year. FDA implemented biennial registration renewal for the 2012 cycle on October 22, 2012, by issuing guidance[28] and upgrading the Food Facility Registration Module (FFRM). The enhancements also included upgraded search functions and improved US Angent identification and verification processes. By enabling biennial registration, the FFRM upgrades and the data collected as a result will improve the agency's ability to respond to food-related emergencies more quickly and efficiently.

Funding History Table with FTE Totals

The following table displays funding and full time equivalent (FTE) staff levels from FY 2010 through FY 2014 for the Foods Program.

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
FY 2010	$783,178,000	$783,178,000	$0	3,387
FY 2011	$836,244,000	$836,244,000	$0	3,605
FY 2012	$866,920,000	$866,920,000	$0	3,546
FY 2013 Annualized CR*	$880,357,000	$863,568,000	$16,789,000	3,684
FY 2014 Request*	$1,106,604,000	$882,817,000	$223,787,000	4,110

**Comparability Adjustments for the Food and Veterinary Medicine Program reorganization and reprogramming approved in FY 2012, that started in FY 2013: -42 FTE and -$7.746M in the Foods Program; -8 FTE and -$1.109M in the Animal Drugs and Feeds Program; +50 FTE and +$8.855M in FDA Headquarters.*

Summary of Budget Request

The FY 2014 budget request for the Foods Program is $1,106,604,000. This amount is an increase of $231,603,000 above the FY 2012 Enacted level. The Center for Food Safety and Applied Nutrition amount in this request is $320,324,000, which supports 994 FTE. The Field amount is $786,280,000, which supports 3,116 FTE. The source of funding for this request is $882,817,000 in budget authority and $223,787,000 in user fees.

The FY 2014 budget request allows the Foods Program to continue to establish a prevention-focused domestic and import food safety system, foster improved diet and nutrition for American consumers, and improve the safety of dietary supplements and cosmetic products. These resources support FDA public health objectives of preventing

[28] "Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Fifth Edition)," Retrieved from http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodDefenseandEmergencyResponse/ucm331959.htm

illnesses caused by contaminated foods, protecting consumers from unsafe products, and supporting improved health and nutrition. The initiatives proposed under the requested budget will allow FDA to achieve HHS and Administration public health priorities, including requirements of the landmark FDA Food Safety Modernization Act of 2011.

Budget Request Details

Pay Increase (Total Program: $3,764,000)

The request for $3,764,000 in total budget authority for the Foods Program reflects a pay increase for civilian and Commissioned Corps staff. The Center's portion of the increase is $1,127,000 and the Field's portion is $2,637,000.

Prioritizing Prevention

Center Activities –
FY 2012 Enacted Base: $71,021,000 (All BA)
FY 2014 Total Increase above Base: (+$22,876,000 / 30 FTE)
FY 2014 Increase above Base for Proposed User Fees (Food Facility Registration and Inspection Fee, Food Import Fee, Food Contact Substances Notification Fee): (+$21,933,000 / 26 FTE)

FY 2014 Initiative Increases above Base:

Transforming Food Safety: Standard-setting for Food and Feed Safety (Proposed Food Facility Registration and Inspection Fee +$8,802,000/ 11 FTE)

Foodborne illnesses linked to known causes are preventable if the parties involved in today's global food chain can be held accountable for implementing appropriate preventive measures at each step of the process where control of hazards is necessary. Standards and guidances are important prevention-focused tools that guide food industry efforts and provide the framework for accountability for meeting appropriate standards called for by FSMA. The more successful the food system is in implementing appropriate preventive measures in the production, processing, transportation, and preparation of foods, the safer the nation's food supply will be.

FDA will continue to develop science-based standards and guidance documents that support industry adoption of preventive controls for food processing and produce safety standards. FDA will also provide education and outreach to growers, industry, and consumers on new safety standards, as well as training and technical assistance to industry, and federal and state regulatory partners in support of implementation of new FSMA standards.

Transforming Food Safety: Import Safety (BA +$943,000 / 4 FTE)

The United States markets are open to food imports from countries with divergent food safety standards and with varying levels of food safety oversight. Approximately 15-20 percent of all foods consumed in the U.S. originate from foreign sources. For example, 80 percent of the seafood and 25-35 percent of the produce eaten by American consumers is imported. To ensure that imported products are as safe as those produced domestically, FDA will develop and implement a variety of approaches to imported food safety, including foreign supplier verification, systems recognition assessments, and improved foreign inspections.

With these resources, FDA will conduct assessments of regulatory food safety systems in countries that export foods to the U.S. to measure their performance against FDA program standards. FDA will use data generated by these assessments to prioritize food safety monitoring activities and thereby enhance the safety of the U.S. food supply.

Transforming Food Safety: Import Safety (Proposed Food Import Fee +$8,583,000 / 8 FTE)

FDA will continue to conduct foreign food safety systems recognition assessments to determine which countries have comparable food safety systems or robust commodity-specific export programs. FDA will also develop and expand partnerships with other public health agencies to execute international outreach, training, capacity building, and technical support.

Proposed User Fee: Food Contact Substances Notification Fee (UF +$4,458,000 / 7 FTE)
With resources funded by user fees, FDA will expand and develop the Food Contact Notification Program (FCN) to ensure stable, long-term viability of the current food contact substances authorization process. This stability and predictability is to the advantage of consumers, FDA, and the regulated industry because the FCN process is simpler, more efficient, and requires fewer resources than the alternative food additive petition process. The user fees will also support continued development and updates of industry guidance, including guidance to address emerging regulatory challenges associated with the use of nanotechnology and endocrine active chemicals in food contact materials. In addition, user fee funds will enable FDA to continue its preeminence in the regulatory science applicable to food contact materials, benefiting both U.S. consumers and industry.

Prioritizing Prevention

Field Activities –
FY 2012 Enacted Base: $111,373,000 (BA: $111,373,000 / UF: $0)
FY 2014 Total Increase above Base: (+$20,228,000 / 26 FTE)

FY 2014 Initiative Increases above Base:

Transforming Food Safety: Integrated Food Safety System (Proposed Food Facility Registration and Inspection Fee +$3,360,000 / 14 FTEs)
With this investment FDA will continue to develop and implement an integrated national food safety system built on uniform regulatory program standards, strong oversight of the food supply, and sustainable multi-year infrastructure investments to provide uniform coverage and safety oversight of the food supply. ORA will conduct the following activities with the resources in this subprogram:

- Hire two FTE to develop and administer ORA food certification programs for inspections, investigators, and analysts at FDA and its regulatory partners to ensure that all parties are performing to the national standard
- Hire three FTE to ensure programmatic objectives and implementation of the Integrated Food Safety System are coordinated and provide support for the governance structure
- Hire six FTE to serve as field state liaisons to assist the States with implementation of the Manufactured Food Regulatory Program Standards
- Hire three FTE to develop and validate certification testing instruments.

Transforming Food Safety: Standard-setting for Food and Feed Safety (Proposed Food Facility Registration and Inspection Fee +$14,000,000 / 0 FTE)
To implement and enforce preventive controls in food processing facilities, FDA will begin training more than 1,100 ORA inspections personnel, as well as 2,300 of FDA's state, tribal, and territorial regulatory partners, in preventive controls inspections and enforcement methods to ensure that inspection personnel are prepared to conduct sound, effective inspections in the new preventive controls framework. FDA will expand the program to also train foreign regulators, third party, and industry representatives in preventive controls and other FSMA policies.

Transforming Food Safety: Import Safety (Proposed Food Import Fee +$2,868,000 / 12 FTE)

With this investment FDA will hire seven FTE to provide outreach and education on FSMA import provisions, including outreach to the import community and other federal agencies involved in the import process. FDA will also hire five FTE to implement a quality management system and quality control measures for the import review process at all locations and provide dedicated quality management measures to assess and assure the consistency of the import review process.

Strengthening Surveillance

Center Activities –
FY 2012 Enacted Base: $135,274,000 (All BA)
FY 2014 Total Increase above Base: (+$20,865,000 / 13 FTE)

FY 2014 Increase above Base for Proposed User Fees (Food Facility Registration and Inspection Fee, Food Import Fee): (+$14,015,000 / 9 FTE)

FY 2014 Initiative Increases above Adjusted Actual Base:

Transforming Food Safety: Integrated Food Safety System (Proposed Food Facility Registration and Inspection Fee +$3,746,000 / 5 FTE)

With these resources, FDA will continue to develop and implement an integrated national food safety system built on uniform regulatory program standards, strong oversight of the food supply, and sustainable multi-year infrastructure investments in state, local, tribal and territorial regulatory and public health partners. These investments will provide more uniform coverage and safety oversight of the food and feed supply.

FDA will evaluate and implement new methods, training, fit-for-purpose method extension, and methods validation manuals, and deploy new instruments to expand laboratory capacity for the integrated national food safety system and support the FSMA mandate for laboratory accreditation.

Transforming Food Safety: Risk Analysis (BA +$3,850,000 / 2 FTE)

Effective prevention strategies and new technologies are needed to reduce these risks to consumers. For example, contaminated produce contributes an estimated 1.29 million illnesses annually in the U.S. at a cost to society of approximately $1.4 million.[29] Risk models provide government and industry with information to evaluate the value of current controls and better characterize the potential effectiveness of new controls to prevent illnesses.

FDA will continue to update FDA's risk ranking and prioritization tools such as iRISK, which is a web-based quantitative risk assessment tool designed to ensure broad accessibility and to facilitate sharing and integration of data between and among FDA and stakeholders. Data generated from these tools will be used to develop predictive risk assessment models, develop a food and feed product tracing system, prioritize resource allocation, measure implementation of produce regulation, and enhance decision making for food safety. In addition to developing and deploying these tools, FDA will support assessments of risk models to ensure the credibility, validity, and accuracy of the information used to inform the FDA decision-making processes.

Transforming Food Safety: Risk Analysis (Proposed Food Facility Registration and Inspection Fee +$2,859,000 / 1 FTE; Proposed Food Import Fee +$2,964,000 / 1 FTE)

[29] Batz, Michael et al. "Ranking the Risk: The 10 Pathogen-Food Combination with the Greatest Burden on Public Health." Retrieved from http://www.rwjf.org/files/research/72267report.pdf

FDA will continue to improve and implement data-driven risk ranking and prioritization tools to inform regulatory, compliance, and resource allocation decision-making critical to the successful implementation of FDA FSMA responsibilities. FDA will also adapt risk analysis tools for use by the public and industry to improve understanding and precision of risk evaluation of FDA-regulated commodities and associated hazards.

Transforming Food Safety: Science for Food Safety (BA +$3,000,000 / 2 FTE)

FDA will invest in science based tools and methods to improve detection of contaminants and adulterants as well as improve rapid screening methods in fresh produce. Understanding factors governing colonization, persistence, and spread of pathogens such as *Salmonella* in fresh produce will result in development of more effective prevention and intervention strategies, as well as improve mitigation steps on the farm and in the farm-to-table continuum.

Additionally, FDA will focus on improved analytical methods, especially rapid screening methods, to support comprehensive post-market surveillance of the food supply. This work will focus on the development of improved extraction, detection, and data analysis procedures for the major classes of contaminants and adulterants in foods, such as pathogens, mycotoxins, heavy metals, and economic adulterants. This work will help FDA focus on achieving high rates of compliance by implementing new enforcement tools.

Transforming Food Safety: Science for Food Safety (Proposed Food Facility Registration and Inspection Fee +$2,183,000 / 1 FTE; Proposed Food Import Fee +$2,263,000 / 1 FTE)

This investment will allow FDA to establish food safety standards that are based on the latest scientific developments and that address hazards from farm-to-table. FDA will also apply research results to improve the speed and effectiveness of import screening.

FDA will develop innovative methods and tools to validate preventive controls and better detect pathogens and chemical contamination in foods, such as *Salmonella*, *E. coli* O157, *Listeria monocytogenes*, Hepatitis A, viruses, and toxins. FDA will also develop and deploy new chemical detection technologies to better identify and address chemical hazards in the food supply both before and after illness occurs. Likewise, FDA will develop new methods and platforms for rapid fingerprinting of foodborne pathogens, along with methods for determining the geographic origin of contaminated food samples, to support rapid, high-throughput analysis in laboratories, in the field, and at the border.

Strengthening Surveillance

Field Activities –
FY 2012 Enacted Base: $286,015,000 (BA: $286,015,000 / UF: $0)
FY 2014 Total Increase above Base: (+$74,925,000/ 102 FTE)
FY 2014 Increase above Base for Prior Proposed User Fees (International Courier User Fee): (+$735,000/ 3 FTE)

FY 2014 Initiative Increases above Base:

Transforming Food Safety: Import Safety (BA +$5,245,000 / 2 FTE)

With this investment, FDA will continue to improve the overall effectiveness of FSMA implementation by providing cross-cutting support to achieve the *FVM Strategic Plan* goals. FSMA IT investments allow FDA to capitalize on pre- and post-market data, scientific research, and current event information to more effectively prevent public health events and ensure the safety of the food supply from farm to table. IT tools, systems, and infrastructure allow FDA to improve and expedite the identification of threats to the public health, and ultimately reduce the incidence of foodborne illness outbreaks. With these resources
ORA will:

- Continue integration of IT systems
- Expand risk targeting for imports in PREDICT by adding new data sources.

Transforming Food Safety: Integrated Food Safety System (Proposed Food Facility Registration and Inspection Fee $1,200,000 / 5 FTE)
With this investment FDA will continue to develop and implement an integrated national food safety system built on uniform regulatory program standards, strong oversight of the food supply, and sustainable multi-year infrastructure investments to provide uniform coverage and safety oversight of the food supply. With these resources, ORA will:

- Hire four FTE to serve as Official Establishment Inventory (OEI) Coordinators for the field
- Hire one FTE with user fees to serve as Scientific Coordinators. This resource will support the states as FDA moves to national standards for laboratories.

Transforming Food Safety: Import Safety (Proposed Food Import Fee $67,745,000 / 92 FTE)

FDA will develop and implement a variety of approaches to ensure the safety of imported foods and feeds. This investment will allow FDA to improve responsiveness to inquiries concerning the import process or the status of imports by establishing a

national call center. The call center will help meet FSMA requirements for industry assistance, improve overall compliance with FSMA rules, and reduce time to solve problems. This investment also supports the design, testing, and implementation of a fee collection system to administer the import user fee program.

This investment will also increase port/border coverage by adding staff and expanding hours of operation, thus providing better screening for food safety while speeding up the overall entry admissibility process for safe products. Moreover, capital investments will be directed to acquire additional space at various border locations to support this effort. This will result in increased efficiency, better industry/FDA communication, reduced time to resolve problems, and improved movement of trade.

In addition, FDA will improve information technology to enhance risk-based decision making for import personnel. IT tools, systems, and infrastructure allow FDA to improve and expedite the identification of threats to the public health, and ultimately reduce the incidence of foodborne illness outbreaks. With these resources, FDA will hire six FTE to implement systems and IT changes to improve the consistency, predictability, and speed of the import review process, by working with industry to enhance the quality of data the agency receives.

FDA also plans to utilize Remote Access Devices to allow field staff to examine shipments and complete all required electronic submissions for data entry on site, print labels for samples collected, and complete collection reports and all necessary documentation. Expedited review, examination, and sampling of products will result in a decrease in the time needed to complete an inspection by providing field staff with the ability to perform the majority of work on site. This technology will also provide opportunities for enhanced targeting of shipments, resulting in greater assurance in the safety of commodities physically examined by FDA.

Likewise, FDA will research, test, validate, and purchase analytical tools for rapid screening of products at the border. The tools will allow for improved risk analytics by permitting targeting of products with the highest probability of being violative and the rapid release of all others into U.S. commerce.

Strengthening Enforcement

Center Activities –
FY 2012 Enacted Base: $22,558,000 (All BA)
FY 2014 Total Increase above Base: (+$5,230,000 / 10 FTE)
FY 2014 Increase above Base for Proposed User Fees (Food Facility Registration and Inspection Fee, Food Import Fee): (+$5,230,000 / 10 FTE)

FY 2014 Initiative Increases above Adjusted Actual Base:

Transforming Food Safety: Foreign Inspections (Food Facility Registration and Inspection Fee +$1,418,000 / 4 FTE)

To ensure that imported products are as safe as those produced domestically, FDA will develop and implement a variety of approaches to imported food safety, including improved foreign inspections.

FDA will plan and evaluate foreign inspections, including review of inspection reports, testing and analysis of samples, development of decision support systems, and management of follow-up compliance actions. FDA will also continue to develop and expand the infrastructure and processes to enable timely enforcement action and follow-up compliance actions related to foreign inspections.

Transforming Food Safety: Domestic Inspections (Food Facility Registration and Inspection Fee +$3,812,000 / 6 FTE)

FSMA recognizes that preventive control standards can only improve food safety to the extent that producers and processors comply with the standards. Therefore, domestic inspection initiatives are essential for FDA to provide oversight, ensure compliance, and respond effectively when problems emerge. Inspections are essential for holding the industry accountable for their responsibility to produce safe products.

FDA will improve enforcement tools and processes and modernize and expand compliance programs to reflect changes introduced by FSMA, including planning inspection work, analyzing trends of violative firms, and identifying firms who are non-compliant or who have not registered as a food establishment with the Agency.

Strengthening Enforcement

Field Activities –
FY 2012 Enacted Base: $167,081,000 (BA: $150,859,000 / UF: $16,222,000)
FY 2014 Total Increase above Base: (+$66,794,000 / 153 FTE)
FY 2014 Increase above Base for Current Law User Fees (Food Reinspection User Fee): (+$309,000 / 0 FTE)
FY 2014 Increase above Base for Current Law User Fees (Food Recall): (+$426,000 / 0 FTE)

FY 2014 Initiative Increases Base:

Transforming Food Safety: Import Safety (BA: +$3,850,000 / 15 FTE)

This investment supports FSMA requirements by establishing an audit staff and developing comparability assessment models to oversee and conduct audits of domestic and international regulatory partners to measure performance against FDA program standards.

ORA will:

- Hire and train 15 FTE including auditors and program managers
- Implement internal procedures
- Collaborate and communicate with key stakeholders on internal integration and operational stand up of the staff
- Perform outreach with external stakeholders on final guidance documents and requirements.

Transforming Food Safety: Import Safety (Proposed Food Import Fee +$50,322,000 / 123 FTE)

This investment will support the implementation of the Foreign Supplier Verification Program, which is a comprehensive prevention-focused import food program that relies more heavily on those in the food supply chain – food manufacturers, processors, packers, distributors, and importers – to provide assurances that the food imported to the U.S are safe and meet regulatory requirements.

In addition, this investment will allow FDA to implement registration verification of foreign firms by conducting a foreign supplier verification program. FDA will hire four FTE to provide program oversight.

Transforming Food Safety: Integrated Food Safety System (BA +$3,850,000 / 15 FTE)

This investment supports implementation of the Integrated Food Safety System by expanding the staff that maintain and oversee assessments and audits of state food contracts. This includes assessments of states enrolled in Manufactured Food Regulatory Program Standards. It also includes collaboration with key FDA stakeholders to enhance training and development that FDA provides to the states.

FDA will modify existing surveillance infrastructure to provide a platform for ongoing high priority pathogen detection in the food supply, expand the number of states engaged in ongoing surveillance, and expand the number and types of commodities under surveillance based on burden of illnesses estimates and food consumption patterns in the United States. FDA will partner with the CDC, U.S. Department of Agriculture and FDA centers to develop rapid strain typing methods for rapid response to foodborne outbreaks.

ORA will:

- Perform 18-month assessments and begin conducting 36-month assessments of States enrolled in the MFRPS
- Collaborate with key FDA stakeholders to provide feedback on assessments to be used to enhance training and development provided to the states by FDA.

Transforming Food Safety: Integrated Food Safety System (Proposed Food Facility Registration and Inspection Fee $8,037,000 / 0 FTE)

With this investment FDA will continue to develop and implement an integrated national food safety system built on uniform regulatory program standards, strong oversight of the food supply, and sustainable multi-year infrastructure investments to provide more uniform coverage and safety oversight of the food supply. ORA will provide funding to federal, state, local, territorial and tribal regulatory and public health partners in the form of at least five states grants, contracts, cooperative agreements or inter-agency agreement between federal agencies. Ten of the state grants, contracts, cooperative agreements or inter-agency agreements between federal agencies will be funded with budget authority and ten will be funded with user fees. ORA also plans to improve, strengthen, and standardize regulatory activities among all partners to ensure consistent oversight, application, and enforcement of food safety laws, and regulations.

Improving Response and Recovery

Center Activities –
FY 2012 Enacted Base: $4,225,000 (BA: $3,761,000 / UF: $464,000)
FY 2014 Total Increase above Base: (+$21,000 / 2 FTE)
FY 2014 Increase above Base for Current Law User Fees (Food Recall): (+$21,000 / 0 FTE)

Field Activities –
FY 2012 Enacted Base: $49,327,000 (BA: $49,327,000 / UF: $0)
FY 2014 Total Increase above Base: (+$240,000 / 1 FTE)

FY 2014 Initiative Increases above Base:

Transforming Food Safety: Planning and Response (Proposed Food Facility Registration and Inspection Fee $240,000 / 1 FTE)
This investment will allow FDA to respond effectively and reduce adverse public health impacts when food safety problems emerge and threaten the health of the American public. This investment will also improve FDA's ability to learn from outbreaks and other food safety incidents and thereby improve future prevention efforts. This funding will also support FDA's ability to enforce mandatory recall authority and respond immediately when a food company fails to voluntarily recall unsafe food.

FDA will work with government and industry partners to develop new traceback tools and new systems that unify information received from FDA regulatory partners and private industry. FDA will fund one FTE to develop and implement traceback procedures.

Nutrition & Labeling Strategies for Better Health

Center Activities –
FY 2012 Enacted Base: $16,691,000 (All BA)
FY 2014 Total Increase above Base: (+$477,000 / 0 FTE)

Reinventing Cosmetics Safety

Center Activities –
FY 2012 Enacted Base: $7,781,000 (All BA)
FY 2014 Total Increase above Base: (+$12,253,000 / 42 FTE)
FY 2014 Increase above Base for Proposed User Fees (Cosmetics User Fee) (+$12,253,000 / 42 FTE)

FY 2014 Initiative Increases above Base:

Proposed User Fee: Cosmetic Safety User Fee (UF +$12,253,000 / 42 FTE)
FDA will use user fee funds to establish a Mandatory Cosmetic Registration Program (MCRP) that will require all domestic and foreign cosmetic labelers marketing products in the U.S. to register their establishments and products with FDA. FDA will provide information gathered from the complete listing of marketed cosmetic products and their ingredients to industry to assist it in its safety evaluations and product modifications. The user fees will also enable FDA to meaningfully participate in international harmonization efforts for cosmetic standards. As a result, FDA will be better positioned to fulfill its public health mission and will promote greater safety and understanding of cosmetic products being used regularly by consumers.

Reinventing Cosmetics Safety

Field Activities –
FY 2012 Enacted Base: $3,253,000 (BA: $3,253,000 / UF: $0)
FY 2014 Total Increase above Base: (+$4,407,000 / 18 FTE)
FY 2014 Increase above Base for Prior Proposed User Fees (Cosmetics User Fee): (+$4,407,000 / 18 FTE)

The user fee investment in the Cosmetics Program will better position FDA to fulfill its public health mission and will promote greater safety and understanding of products being used regularly by consumers. With this investment, FDA will refine inspection and sampling of imported products and apply risk-based approaches to post-market monitoring of domestic and imported products, inspection, and other enforcement activities.

FOODS PROGRAM ACTIVITY DATA

PROGRAM WORKLOAD AND OUTPUTS	FY 2012 Actual	FY 2013 CR	FY 2014 Request
FOOD AND COLOR ADDITIVE PETITIONS			
Petitions Filed [1]	13	10	10
Petitions Reviewed [2]	6	7	7
PREMARKET NOTIFICATIONS FOR FOOD CONTACT SUBSTANCES			
Notifications Received	107	114	114
Notifications Reviewed [3]	102	100	100
INFANT FORMULA NOTIFICATIONS			
Notifications Received [4]	24	35	35
Notifications Reviewed [5]	24	35	35
FDA Review Time	90 Days	90 Days	90 Days
NEW DIETARY INGREDIENT NOTIFICATIONS [6]			
Submissions Received [7]	45	50	50
Submissions Reviewed [8]	45	50	50
FDA Review Time	75 Days	75 Days	75 Days

[1] This number is for the cohort of petitions filed in the FY.

[2] Number reviewed includes petitions approved, withdrawn, or placed in abeyance because of deficiencies during the FY.

[3] Number reviewed includes notifications that became effective or were withdrawn.

[4] A notification may include more than 1 infant formula.

[5] Number of submissions reviewed includes some submissions that were received in the previous FY.

[6] A single notification may address one or more new dietary ingredients. For example, FDA has received at least 15 notifications that pertain to 2 up to 16 new dietary ingredients in a single notification.

[7] Number of submissions received in current FY includes some received late in the FY that are expected to be completed in the next FY when the due date occurs.

[8] Number of submissions reviewed in the current FY includes some submissions that were received in the previous FY when the due date occurred in the current FY.

Combined Field Activities – ORA
Program Activity Data

Field Foods Program Activity Data (PAD)

Field Foods Program Workload and Outputs	FY 2012 Actual		FY 2013 Estimate	FY 2014 Request
FDA WORK				
DOMESTIC INSPECTIONS				
UNIQUE COUNT OF FDA DOMESTIC FOOD ESTABLISHMENT INSPECTIONS	***10,086***		***10,326***	***10,326***
Domestic Food Safety Program Inspections	7,523		Activities no longer planned to this level due to enactment of FSMA and alignment of resources into only high and low risk categories.	Activities no longer planned to this level due to enactment of FSMA and alignment of resources into only high and low risk categories.
Imported and Domestic Cheese Program Inspections	266			
Domestic Low Acid Canned Foods/ Acidified Foods Inspections	382			
Domestic Fish & Fishery Products (HACCP) Inspections	1,422			
Import (Seafood Program Including HACCP) Inspections	252			
Juice HACCP Inspection Program (HACCP)	259			
Interstate Travel Sanitation (ITS) Inspections	1,053			
Domestic Field Exams/Tests	3,513		3,945	3,945
Domestic Laboratory Samples Analyzed	10,621		11,300	11,300
FOREIGN INSPECTIONS				
UNIQUE COUNT OF FDA FOREIGN FOOD ESTABLISHMENT INSPECTIONS	***1,347*** [2]		***1,200***	***1,200*** [1]
All Foreign Inspections	1,347		1,200	1,200
TOTAL UNIQUE COUNT OF FDA FOODS ESTABLISHMENT INSPECTIONS	***11,433***		***11,526***	***11,526***
IMPORTS				
Import Field Exams/Tests	171,783		160,200	160,200
Import Laboratory Samples Analyzed	29,966		35,300	35,300
Import Physical Exam Subtotal	**201,749**		**195,500**	**195,500**
Import Line Decisions	10,805,094		11,482,234	12,201,809
Percent of Import Lines Physically Examined	1.87%		1.70%	1.60%
Prior Notice Security Import Reviews				
(Bioterrorism Act Mandate)	81,888		80,000	80,000
STATE WORK				
UNIQUE COUNT OF STATE CONTRACT FOOD ESTABLISHMENT INSPECTIONS	***9,306***		***10,523***	***10,523***
UNIQUE COUNT OF STATE PARTNERSHIPS FOOD ESTABLISHMENT INSPECTIONS	***430***		***273***	***273***
State Contract Food Safety (Non HACCP) Inspections	8,161		9,318	9,318
State Contract Domestic Seafood HACCP Inspections	1,062		1,104	1,104
State Contract Juice HACCP	69		103	103
State Contract LACF	76		68	68
State Partnership Inspections	430		273	273
State Contract Foods Funding	$12,699,510		13,076,000	13,076,000
Number of FERN State Laboratories	19		19	19
Number of Food Safety State Laboratories	15		15	15
Annual FERN State Cooperative Agreements/Operations Funding	$16,136,000		$18,455,000	$18,455,000
Total State & Annual FERN Funding	**$28,835,510**		**$31,531,000**	**$31,531,000**
GRAND TOTAL FOOD ESTABLISHMENT INSPECTIONS	***21,169***		***22,322***	***22,322***

[1] For investigators hired with FY 2014 BA funding received through the Office of International Programs (OIP) for the China Import Safety Initiative, the full performance year is FY 2016. During the full performance year (FY 2016), the FY 2014 funding increase for inspections will allow OIP to conduct an additional 135 foreign food safety inspections. Please also see the FDA Headquarters /OIP narrative for further information.

[2] The FY 2012 actual unique count of foreign inspections includes 42 OIP inspections (10 for China and 32 for India).

Combined Field Activities – ORA
Program Activity Data

Field Cosmetics Program Activity Data (PAD)

Field Cosmetics Program Workload and Outputs	FY 2012 Actual	FY 2013 Estimate	FY 2014 Request
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA COSMETICS ESTABLISHMENT INSPECTIONS	***100***	***100***	***100***
Domestic Inspections	100	100	100
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA COSMETICS ESTABLISHMENT INSPECTIONS	***0***	***0***	***0***
Foreign Inspections	0	0	0
IMPORTS			
Import Field Exams/Tests	1,600	1,600	1,600
Import Laboratory Samples Analyzed	0	630	630
Import Physical Exam Subtotal	**1,600**	**2,230**	**2,230**
Import Line Decisions	2,389,000	2,602,764	2,883,187
Percent of Import Lines Physically Examined	0.07%	0.09%	0.08%
GRAND TOTAL COSMETICS ESTABLISHMENT	***100***	***100***	***100***

Humans Drugs Program

The following table displays the funding and full time equivalent (FTE) staffing levels for FY 2012 through FY 2014.

FDA Program Resources Table

(Dollars in thousands)

	FY 2012		FY 2013[1]	FY 2014	FY 2014 +/-
	Enacted	Actuals	CR	Request	FY 2012
Program Level	**$978,705**	**$954,596**	**$1,267,937**	**$1,292,175**	**+$313,470**
Center	$838,694	$818,077	$1,073,726	$1,097,091	+$258,397
FTE	3,281	3,272	3,644	3,917	+645
Field	$140,011	$136,519	$194,211	$195,084	+$55,073
FTE	790	767	934	965	+198
Program Level FTE	**4,071**	**4,039**	**4,578**	**4,882**	**+843**
Budget Authority	**$477,810**	**$477,623**	**$480,735**	**$465,950**	**-$11,860**
Center	$347,817	$347,633	$349,946	$339,414	-$8,403
Field	$129,993	$129,990	$130,789	$126,536	-$3,457
Budget Authority FTE	**2,040**	**1,933**	**1,997**	**2,019**	**86**
Center	1,301	1,213	1,265	1,299	86
Field	739	720	732	720	0
User Fees	**$500,895**	**$476,973**	**$787,202**	**$826,225**	**+$325,330**
Center PDUFA	$490,877	$470,444	$505,745	$534,526	+$43,649
FTE	1,980	2,059	2,070	2,115	+56
Field PDUFA	$10,018	$6,529	$10,321	$10,908	+$890
FTE	51	47	47	47	-
Center Generic Drugs	0	0	$202,731	$207,475	+$207,475
FTE	0	0	250	444	+444
Field Generic Drugs	0	0	$51,811	$53,023	+$53,023
FTE	0	0	150	173	+173
Center Biosimilar User Fee	0	0	$15,304	$15,676	+$15,676
FTE	0	0	59	59	+59
Field Biosimilar User Fee	0	0	$1,290	$1,322	+$1,322
FTE	0	0	5	5	+5
Field International Courier[2] Fee	0		0	$491	+$491
FTE	0	0	0	2	+2
Field Medical Products Reinspection User Fee[2]	0	0	0	$2,804	+$2,804
FTE	0	0	0	18	+18
User Fees FTE	**2,031**	**2,106**	**2,581**	**2,863**	**+757**

[1] Spending authority has been adjusted pursuant to PL 112-175, Section 101(c) for the applicable user fee programs.
[2] Proposed user fee.

The FDA Human Drugs Program operates under the following legal authorities:

Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 321-399)
Public Health Service Act of 1944 (42 U.S.C. 201)
Federal Advisory Committee Act (FACA) of 1972 as amended
Orphan Drug Act of 1983 (21 U.S.C. 360ee)
Drug Price Competition and Patent Term Restoration Act of 1984 (Section 505(j) 21 U.S.C. 355(j)) (a.k.a. "Hatch Waxman Act")
Prescription Drug Marketing Act (PDMA) of 1987 (21 U.S.C. 353)
Anti-Drug Abuse Act of 1988
Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 201)
Orphan Drug Amendments of 1988
Generic Drug Enforcement Act of 1992
Prescription Drug User Fee Act (PDUFA) of 1992
FDA Export Reform and Enhancement Act of 1996
Food and Drug Administration Modernization Act (FDAMA) of 1997*
Public Health Security and Bioterrorism Preparedness and Response Act of 2002
Best Pharmaceuticals for Children Act (BPCA) of 2002
Freedom of Information Act (FOIA) as amended in 2002 (5 U.S.C. § 552)
Pediatric Research Equity Act (PREA) of 2003
Project Bioshield Act of 2004 (21 U.S.C. 360bbb-3)
Food and Drug Administration Amendments Act (FDAAA) of 2007*
Public Health Service Act of 2010 (42 U.S.C. 262)
Protecting Patients and Affordable Care Act of 2010*
Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA)

Allocation Method: Direct Federal/Intramural

Program Description and Accomplishments

FDA's Human Drugs Program is responsible for ensuring the safety and efficacy of prescription, generic, and over-the-counter (OTC) drugs that are available to Americans. The Program is also responsible for monitoring marketed drugs to ensure patient safety, and monitoring drug quality to ensure the safety of the drug supply chain. The Center for Drug Evaluation and Research (CDER) and the Office of Regulatory Affairs' (ORA) field drugs program comprise FDA's Human Drugs Program, which operates with funding from appropriations and user fees.

CDER promotes and protects public health by ensuring safe and effective drugs are available to Americans. This mission supports FDA priorities of improving healthcare quality and reducing healthcare costs.

*Authorities under this act do not appear in sequence in the U.S. Code. The authorities are codified as amended in scattered sections of 21 U.S.C.

The FDA Safety and Innovation Act (FDASIA) was signed into law on July 9, 2012. FDASIA includes the reauthorization of the Prescription Drug User Fee Act (PDUFA), and authorizes the Generic Drug User Fee Amendments (GDUFA) and Biosimilar User Fee Act (BsUFA). Additional resources from these user fee programs will enhance CDER's ability to promote and protect public health.

Globally, ORA ensures the safety and efficacy of human drugs through pre-market and post market inspections of domestic and foreign manufacturers. These inspections are conducted by highly trained investigators, many of whom have completed a certification program and demonstrate their knowledge, competence, and professionalism while conducting inspections of high-risk firms. ORA works closely with CDER in identifying which manufacturing sites to inspect and determining appropriate regulatory actions to take when significant violations are found.

At the U.S. borders, ORA determines product admissibility. Determining admissibility includes performing entry reviews, field exams, and sample collections to ensure that products coming into the United States are from approved sources and are properly registered.

ORA Field offices support Human Drugs Program activities by:

- Advising FDA leadership on enforcement, import, inspection, and laboratory policies
- Assessing industry compliance with applicable regulations to protect the public health
- Conducting risk-based domestic and foreign pre market and post market inspections of drug manufacturers to assess their compliance with Good Manufacturing Practices (GMP)
- Performing laboratory analyses to support inspections and verify compliance;
- Overseeing the regulated products on a surveillance or "for cause" basis
- Responding to emergencies and investigating incidents of product tampering and responding to natural or intentional disasters that may affect FDA-regulated goods
- Developing criminal cases to address the marketing of counterfeit products through the Office of Criminal Investigations (OCI) and the Forensic Chemistry Center (FCC).

The Human Drugs Program executes its regulatory responsibilities in the following subprograms:

- New Drug Review
- Generic Drug Review
- Drug Quality
- Post Market Safety Oversight
- Oversight of Drug Promotion

New Drug Review – Center Activities
Base Amount: $440,970,000 (BA: $119,256,000 / UF: $321,714,000)

Public Health Focus

The New Drug Review subprogram involves evaluating the safety and efficacy of medical products before those products are marketed to the public. The goal of the New Drug Review subprogram is to promote the health of the public by ensuring that prescription and OTC drug products are safe and effective. In addition, CDER aims to ensure that novel prescription drug therapies become available in a timely manner without compromising high standards of safety and efficacy.

Key functions in the New Drug Review subprogram include:

- Clinical Review – CDER reviews clinical research data submitted by pharmaceutical
- companies to demonstrate safety and efficacy of new drug products. If a drug is shown to be effective and if its health benefits outweigh its risks, CDER may approve the drug for marketing in the United States.
- Bioresearch Monitoring – CDER monitors the research of pharmaceutical companies conducted through clinical trials to ensure the safety of study participants, as well as to verify the quality and integrity of scientific data. Specifically, CDER conducts on-site inspections of clinical trial study sites, institutional review boards, sponsors, study monitors, and contract research organizations.
- Pharmaceutical Science and Chemistry Review – CDER maintains a corps of highly-talented experts who ensure that the drug review process results in a thorough understanding of how drugs are designed, produced, and delivered to patients. Through such understanding, CDER staff can ensure that drugs available to American patients are safe and effective.
- Pediatrics – To ensure the protection of children who need prescription and Over-The-Counter (OTC) drugs, Congress enacted several laws to promote drug development for children. CDER works with pharmaceutical companies to conduct studies of products for children to promote safety and efficacy of pediatric drug products.
- Review of Over-The-Counter (OTC) Products – CDER reviews and evaluates OTC drugs to ensure they are safe, effective, and of high quality. CDER also ensures consumers are well-informed about how to best use OTC drugs by working with industry to provide clear, easy-to-read drug information. The trend to self-medicate has increased greatly among patients in recent years, and CDER's role is critical to promote safety among patients using OTC products.

- Pre-Approval Inspections – Before an application for a new drug product is approved, FDA inspects the product's manufacturing and development facilities to verify they meet FDA's standards for good manufacturing practices. FDA inspectors must ensure that a drug product is manufactured consistently and meets high standards of quality.

Public Health Outcome

Efficient, accurate, and thorough reviews allow for the availability of safe and effective drugs to consumers. Without consistent dedication to conducting thorough reviews, patients might be at risk of adverse events resulting from unsafe drug products on the market. The pre-market activities associated with reviewing new drugs and inspections of facilities are conducted to pursue FDA's mission to promote and protect the public health.

<u>New Drug Review</u> – Field Activities
Base Amount: $35,684,000 (BA: $25,666,000 / UF: $10,018,000)

The public health focus of ORA under the New Drug Review subprogram is to assess whether methods and facilities used for manufacturing, processing, and testing of products submitted under New Drug Applications (NDAs) are adequate to ensure strength, quality, and purity.
ORA inspects establishments to verify their ability to manufacture products to the specifications stated in the application. ORA also confirms the authenticity of the data contained in the application and reports any information which may impact the firm's ability to manufacture the product in compliance with GMP. Inspectional coverage is necessary to assure that NDAs are not approved if the applicant has not demonstrated the ability to operate with integrity and in compliance with all applicable requirements. ORA conducts Bioresearch Monitoring Program (BIMO) inspections of scientific studies which are designed to develop evidence to support the safety and effectiveness of investigational drugs. Physicians and other qualified experts ("clinical investigators") who conduct these studies are required to comply with applicable statutes and regulations intended to ensure the integrity of clinical data on which product approvals are based and, for investigations involving human subjects, to help protect the rights, safety, and welfare of these subjects.

Public Health Outcome

In an effort to increase public awareness and knowledge, FDA shares a series of lists on its website containing information on clinical investigators who:

- Received notification from the Agency of the intent to initiate administrative proceedings to determine if the person should be disqualified from receiving investigational products

- Are disqualified or 'totally restricted' and are no longer eligible to receive investigational drugs, biologics, or devices
- Have been recommended for disqualification
- Agreed to certain restrictions
- Agreed to restrictions which have been subsequently removed
- Provided FDA with adequate assurances of their future compliance with requirements applicable to the use of investigational drugs and biologics.

FDA also makes available a separate list of firms or persons who have been debarred under Section 306 of the Federal Food, Drug and Cosmetic Act.

Based on referrals from the OCI and other sources, ORA debars individuals with criminal convictions from participating in certain aspects of human drug industry activities.

While FDA is actively engaged in regulating industry, the agency is working with industry to prevent drug shortage situations from arising from a variety of causes such as the unavailability of active ingredients or the failure to comply with current good manufacturing practices. ORA works with the FDA Centers when potential product shortage situations are identified during inspections or when ORA field offices are notified by drug manufacturers of potential supply disruptions. To support FDA's ongoing efforts to prevent and resolve prescription drug shortages, ORA developed and issued a specific Import Bulletin to field offices, outlining enforcement discretion of specific product and manufacturer combinations to help prevent or alleviate potential drug shortage issues.

This Import Bulletin was issued during FY 2012, and updated twelve times to reflect new product and manufacturer combinations, or to update existing product and manufacturer combinations. While ORA is aware of the impact of drug shortages on the public, ORA's mission in conducting inspections to assess compliance with the laws and regulations does not change. The agency strives to ensure the availability of quality drug products for the public through a balanced and risk-informed approach.

In FY 2012, ORA expanded its drug testing capabilities to include antimicrobial effectiveness testing methodology in three separate ORA field laboratories. The results of the analytical findings were provided to the Center for Drug Evaluation and Research (CDER) for use by their reviewers during review and evaluation of new drug applications. The data provided by ORA imparts new and important information needed in the evaluation and Center determination of product stability.

A critical part of ORA's mission is the pre-market evaluation of drugs. To accomplish these evaluations, the FDA relies on information submitted by sponsors of research and marketing applications. The Bioresearch Monitoring Inspection Program, which includes Clinical Investigator, Institutional Review Board (IRB), Sponsor/Monitor/Contract Research Organization (CRO) and In Vivo Bioequivalence inspections, audits the

quality of data submitted by sponsors in support of these research or marketing applications. These inspections are also responsible for ensuring the rights, safety and welfare of research participants are maintained during the conduct of these clinical trials.

Every year bioresearch monitoring inspections uncover instances of false data and incorrect treatment of study participants. FDA has subsequently rejected study data, suspended application review, disqualified clinical investigators, and pursued criminal prosecution. For example, in fiscal year 2012, establishments were cited for: failing to maintain accurate case histories with respect to observations and data pertinent to the study, enrolling subjects who did not meet inclusion/exclusion criteria, not obtaining informed consents, and not documenting that the human subjects were in a life-threatening situations.

During bioequivalence studies, establishments were cited for several violations, such as failing to conduct a clinical investigation in accordance with the signed investigational plan and failing to prepare or maintain adequate and accurate records with respect to observations and data pertinent to clinical investigations and bioanalytical studies. Moreover, there was a failure to either establish standard operating procedures or existing procedures were inadequate or not followed during the conduct of clinical investigations and bioanalytical studies.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2013
223201: Percentage of Standard NDAs/BLAs within 10 months. *(Output)*	FY 2011: 99% Target: 90% (Target Exceeded)	90%	N/A	N/A
223202: Percentage of Priority NDAs/BLAs within 6 months *(Output)*	FY 2011: 95% Target: 90% (Target Exceeded)	90%	N/A	N/A
223206: Review and act on 90 percent of standard NME NDA and original BLA submissions within 10 months of the 60 day filing date.	N/A New Goal*	N/A	90%	N/A

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2013
223207: Review and act on 90 percent of priority NME NDA and original BLA submissions within 6 months of the 60 day filing date.	N/A New Goal*	N/A	90%	N/A
223208: Review and act on 90 percent of standard non-NME original NDA submissions within 10 months of receipt.	FY 2011: 98% (Historical Actual) New Goal*	N/A	90%	N/A
223209: Review and act on 90 percent of priority non-NME original NDA submissions within 6 months of receipt.	FY 2011: 100% (Historical Actual) New Goal*	N/A	90%	N/A

***** To align with the new PDUFA V performance commitments starting in FY 2013, goals 223201 and 223202 were deleted and goals 223206, 223207, 223208 and 223209 were added.

Generic Drug Review – Center Activities
Base Amount: $87,936,000 (BA: $87,936,000/ UF: $0)

Public Health Focus

CDER's generic drug review subprogram is part of the larger generic drugs program, which includes additional functions related to generic drugs throughout the Center. CDER's generic drug review subprogram concentrates specifically on the review process. Other non-review work (mainly post market work) within the generic drugs program is captured in other parts of CDER's budget.
Every year, CDER expands the availability of high-quality generic drugs and provides consumers and healthcare providers with information on both safety and effectiveness. With each new generic version of a brand-name drug approved by FDA, consumers have an additional option to save money on prescription drug needs. Key functions in the generic drug review subprogram include:

- Generic Drug Application Review – The basic requirements for approval of generic drugs are the same as for new drug approvals, although the generic drug manufacturer does not need to repeat the safety and efficacy studies conducted by the developer of

the original product. Prior to approval, generic drug sponsors are required to demonstrate bioequivalence – that the active ingredient in a generic product is absorbed at a rate and extent similar to the brand name product.

- Pre-Approval and Bioequivalence Lab Inspections – FDA inspects manufacturing facilities of generic drug products before approving an application. In addition, FDA inspects laboratories where bioequivalence studies were conducted to ensure accuracy and integrity of data submitted in generic drug applications.
- Regulatory Policy – CDER frequently evaluates and responds to citizen petitions related to upcoming actions on generic drug applications. FDA receives numerous petitions through which it is asked to take – or refrain from taking – an action on a generic drug application. CDER reviews these petitions, taking into account the scientific issues raised, and prepares responses for various stakeholders.
- Research into Bioequivalence Technologies – Some types of drugs are very difficult for generic companies to duplicate. In cases like these, CDER is eager to understand how to assess bioequivalence as a way to encourage development of generic alternatives, further opening the doors to lower-priced alternatives and better access to drugs for patients.

Public Health Outcome

Generic drug review is a high priority for CDER, and this function supports the larger FDA mission of promoting and protecting public health. The availability of generic drugs directly impacts public health by making safe, affordable drug products accessible to the public. With increasing healthcare costs, many Americans face challenges in acquiring the drug products necessary for proper medical treatment. The availability of safe, effective, and affordable generic drugs makes it possible for more patients to afford essential medicines.

During FY 2012, CDER approved or tentatively approved 619 generic drug applications. The total number of actions taken on Abbreviated New Drug Applications (ANDA) – including approvals, tentative approvals, not approvable actions, and approval actions – in FY 2012 was 2,313.

Generic Drug Review – Field Activities
Base Amount: $8,029,000 (BA: $8,029,000 / UF: $0)

Public Health Focus

ORA's public health focus under the Generic Drug Review subprogram is to assess whether the methods and facilities used for the manufacturing, processing, and testing of products submitted under an Abbreviated New Drug Application (ANDA) are adequate to ensure strength, quality, and purity.

Public Health Outcome

ORA supports the generic drug program through pre-approval and post-approval inspections to verify application data and assess the firm's ability to manufacture products in accordance with CGMP. ORA also conducts inspections of bioequivalence studies to substantiate source data and verify accuracy, completeness and regulatory compliance.

In FY 2012, ORA collaborated with CDER to develop a priority listing of Abbreviated New Drug Applications (ANDA) inspections, aiding in targeting inspectional resources and creating Agency efficiencies by identifying generic drug manufacturing facilities for inspection to coincide with Center reviews of applications.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
223205: The total number of actions taken on abbreviated new drug applications in a fiscal year *(Output)*	FY 2012: 2,313 Target: 2,000 (Target Exceeded)	2,000	2,500	+500

Drug Quality – Center Activities

Base Amount: $100,171,000 (BA: $44,020,000 / UF: $56,151,000)

Public Health Focus

CDER's drug quality subprogram includes functions to ensure that drugs meet FDA standards of quality. CDER's drug oversight activities begin when sponsors test drug products in animals. CDER's oversight function continues throughout the drug lifecycle, including post market safety activities. CDER also scrutinizes generic drug products to ensure they demonstrate equivalent performance to the innovator product. CDER is fully engaged in enforcement actions against drug products that exist outside of the FDA approval system, such as counterfeit and marketed unapproved products.

CDER provides comprehensive regulatory coverage of the production and distribution of drug products, and manages inspection programs designed to minimize consumer exposure to defective or harmful drug products. CDER evaluates the findings of inspections that examine the conditions and practices in facilities where drugs are manufactured, packed, tested, and stored. CDER also monitors the quality of finished drug products in distribution through sampling and analysis.

In addition, CDER sets guidelines for drug quality and manufacturing processes. CDER's team of inspectors and quality management experts work to ensure that any change to a manufacturing process does not adversely affect the safety or efficacy of the drug produced. CDER also evaluates reports about suspected problems from manufacturers, healthcare professionals, and consumers.

Public Health Outcome

Assessing drug quality supports CDER's initiative to make safe and effective drugs available to the public, as well as protecting the safety and integrity of the drug supply chain. This reduces risks associated with adverse events resulting from poor quality or defective drug products. As a result, consumers face fewer risks associated with unsafe drugs and are increasingly protected from drugs that do not meet FDA standards of quality.

Drug Quality – Field Activities
Base Amount: $91,884,000 (BA: $91,884,000 / UF: $0)

Public Health Focus

ORA minimizes consumers' risk of exposure to defective drug products by conducting inspections, monitoring imports, and collecting and analyzing product samples of domestic and foreign drug manufacturers. These activities prevent marketing of, or remove from the market, violative drug products. Early detection of contaminated or defective human drug products and their ingredients continues to be a priority within ORA.

ORA field offices investigate and build enforcement cases using a number of enforcement tools such as seizures, injunctions, and prosecutions. ORA is also responsible for oversight and monitoring of recalls conducted by the drug industry, assuring that the companies' recall efforts progress satisfactorily and are effective in removing defective products from commerce.

All ORA Laboratories implemented a quality system in accordance with the International Standard (ISO 17025) through sharing of data and other information with accredited labs around the world. Accreditation of laboratory quality management systems provides a mechanism for harmonizing and strengthening processes and procedures, thereby improving the quality of operations and the reliability of FDA's science. In 2012, all thirteen ORA laboratories maintained their lab accreditation from a third party.

The National Check Sample Program (NCSP) continues to be implemented by all ORA laboratories. Successful completion of all proficiency testing rounds were executed by all ORA laboratories to ensure the validity of laboratory results for tests performed, which in turn demonstrates technical competency of all ORA laboratory personnel.

Public Health Outcome

ORA continues to pilot and implement portable analytical tools for use by ORA import investigators during day to day operations. The tools allow ORA investigators to perform limited analytical screening of a variety of FDA regulated products to detect high level contaminants such as toxic elements or presence of Active Pharmaceutical Ingredients (APIs) in products labeled as dietary supplements at the time the products are offered for import into the U.S. In FY2012, ORA implemented daily use of two different portable devices at limited locations throughout the nation.

One of the tools in use allows ORA investigators to screen imported dietary supplements for the presence of APIs. After screening more than 200 products, ORA investigators found 44 of the products screened positive for the presence of APIs. Full analysis performed by ORA laboratories found all 44 products contained sibutramine, an un-labeled API, at levels actionable by the Agency. Sibutramine is known to substantially increase blood pressure and/or pulse rate and may present a significant risk for people with a history of coronary artery disease, congestive heart failure, arrhythmias or stroke. ORA has subjected the product to detention without physical examination and also worked with our Customs and Border Protection (CBP) partners to seize these shipments and keep these dangerous products out of the U.S. market. ORA continues to work with CDER to identify new portable analytical tools, and new uses for existing tools, for use by ORA investigators.

ORA field laboratories conducted enhanced drug surveillance activities during FY 2012. Over 150 products were tested as part of the program. Active Pharmaceutical Compounds intended for pharmacy compounding, identified as at-risk for economic adulteration, were targeted for analysis. Drug surveillance activities involving microbiological screening for drug products considered at risk for microbiological contamination were also implemented.

ORA laboratories fully support the Health and Human Services (HHS) plan for medical countermeasures. This support is done under the auspices of the joint FDA and Department of Defense (DoD) shelf life extension program. FDA conducts the comprehensive testing and evaluation that determines whether adequate supporting data are available to extend the expiration date of specified lots of stored drug products owned by DoD, the Strategic National Stockpile (SNS) and the Veterans Administration (VA). ORA laboratory testing led to the extension of 1,893 lots in FY 2012.

ORA is in the second of a three year Cooperative Research & Development Agreement (CRADA) with the United States Pharmacopeia (USP) to participate in certification of USP reference standards, USP monograph modernization, and activities relating to economically motivated adulteration (EMA). These initiatives promote drug quality and efficacy which are vital in promoting public health. To date, ORA has completed over 40 reference standard certifications and participated in updating 3 USP monographs. Initiatives and work planning are ongoing in relation to the CRADA efforts.

ORA continues to collaborate with CDER in a Pharmacy Compounding Validation program to identify the most commonly compounded medications and develop and validate unofficial standardized testing methods. As of August 1, 2012, ORA has validated testing methods for 10 commonly compounded drug products. The program ensures specialized drug products are analyzed appropriately to ensure quality, consistency, and efficacy for pharmacy compounded products.

The foreign drug inspection program continues to emphasize more surveillance driven foreign inspections as opposed to application driven foreign inspections. A total of 813 foreign drug inspections covering 62 different countries were conducted in FY 2012, exceeding the total completed in FY 2011 by 86 inspections. The dedicated foreign drug cadre completed 212 or 26 percent of these inspections, while the global offices in India and China were responsible for 59 or 7 percent of these inspections. This experienced group of investigators had some significant outcomes. Of the 28 GMP based foreign warning letters issued by CDER in FY 2012, 13 or 46 percent have been issued from inspections conducted by either the dedicated foreign drug cadre or global offices. A sampling of some of the specific FY 2012 warning letters that led to positive public health outcomes is as follows:

- A warning letter was issued to an active ingredient penicillin manufacturer in Poland. The manufacturer was not taking appropriate controls in order to minimize contamination in non-penicillin manufacturing areas. As a result of this inspection, the firm was added to a Detention Without Physical Examination (DWPE) Import Alert, thereby preventing unsafe products from entering the U.S. market.
- Another warning letter was issued to an active ingredient manufacturer in Mexico. This initial FDA inspection of a site shipping non-application products. The firm's quality unit failed to establish written procedures for monitoring the appropriate processing steps and failed to review and approve all appropriate quality documents. As a result of the adverse inspection findings, the firm was added to a DWPE Import Alert and the firm's products were prevented from entering the U.S. market.
- Similarly, a warning letter was issued to a medical dressing manufacturer in China. This initial FDA inspection revealed the firm was shipping antiseptic wipes, purported to be sterile, that were contaminated with microorganisms. The firm failed to establish and follow written procedures to prevent objectionable microorganisms as well as failing to validate all its sterilization processes. As a result of the adverse inspection findings, the firm was added to a DWPE Import Alert, thereby preventing unsafe products from entering the U.S. market.

ORA monitors recall of human drugs that have been found to present safety concerns, and assures the adequacy of the firm's recall to effectively remove defective products from commerce. Through the classification process, the Center determines the level of

public health risk the product presents. Appropriate public notification is also a component of the agency's recall program. In FY2012, FDA classified and issued recall numbers for 28 Class I, 194 Class II, and 94 Class III recalls of human drug products.

In support of the President's Transparency Initiative, ORA started posting on the internet the most common inspection observations of objectionable conditions or practices that are made during inspections. This information includes inspectional observation summaries from FY 2006 through FY 2012. Additionally, a searchable database of inspected facilities with FDA inspection classifications is posted that represents the final inspection classification for inspections conducted of clinical trial investigators, IRBs, and facilities that manufacture, process, pack, or hold an FDA-regulated product that is currently marketed.

Disclosure of this data will provide the public and regulated industry with more information about company practices that may jeopardize public health, and about companies that are complying with the law. These websites premiered in May 2011.

During the first ten months of FY 2012, there have been two injunctions filed against drug firms and two seizures executed against drug products. These enforcement actions protect patient safety by assuring that manufacturers comply with laws and that violative products are not distributed into U.S. commerce.

In instances of criminal activity, ORA's OCI is expanding efforts to develop cases that address the marketing of counterfeit products. The increasing globalization of crime has created new challenges to law enforcement. OCI coordinates counterfeit drug investigations with several foreign counterparts, especially those in China, Israel, Canada and the United Kingdom. These efforts continue to produce positive outcomes for both OCI and its foreign counterparts. OCI continues to aggressively pursue counterfeit drug investigations with law enforcement partners in foreign countries as well as with Federal, State, local, tribal, and territory law enforcement here in the U.S.

During FY 2012, ORA's OCI made 249 drug related arrests, and secured 201 drug related convictions with fines, restitutions and other monetary penalties in excess of $4.9 billion.

A sampling of some of the specific FY 2012 case activity that led to positive public health outcomes is as follows:

- Distribution of Adulterated and Misbranded Cancer Treatment Drugs - In June 2012, a California woman was convicted of distributing adulterated cancer drugs from overseas to a Missouri doctor and others. In May 2012, the Missouri doctor receiving the drugs was likewise convicted after pleading guilty to one misdemeanor count of receiving misbranded prescription drugs, including cancer

treatment drugs marketed in the United States as Neupogen, Herceptin, and Rituxan. This doctor also agreed to pay a civil settlement of over one million dollars to resolve allegations that he submitted false claims to government health care programs for assorted misbranded cancer treatment drugs and agreed to be excluded from future participation in federal health care programs for seven years.

In February 2012, a third defendant pled guilty to one count of conspiracy to cause the introduction of adulterated prescription drugs into interstate commerce. This defendant was later sentenced to 24 months in prison and agreed to forfeit approximately $1.4 million dollars that was seized during the investigation.

- Misbranded Drugs – Colchicine Toxicity Causes Death in Patients - In April 2012, a Texas compounding pharmacy and its owner pled guilty to two criminal violations of the Food, Drug, and Cosmetic Act (FDCA). The pleas were in conjunction with the compounding pharmacy's interstate shipment of two lots of colchicine injectable solution that led to the deaths of three people in the Pacific Northwest. At the time of production of the colchicine the pharmacy did not test their product for potency. FDA laboratory analysis of several vials of colchicine that were collected from the pharmacy showed some were super-potent and some were sub-potent making them misbranded because the actual levels of colchicine did not correspond with the levels listed on the vial labels.

OCI's criminal investigation and successful prosecution of these types of cases serve FDA's mission by protecting the public health from dangerous products and also provided a strong message to firms that impede FDA regulatory processes.

OCI Proactive Ongoing Initiatives:

- Operation Pangea - Between September 25 and October 2 2012, OCI participated in the fifth annual International Internet Week of Action (IIWA), a global cooperative effort to combat the online sale and distribution of potentially counterfeit and illegal medical products. Dubbed "Operation Pangea V," OCI partnered with regulatory enforcement units from CDER, ORA's Division of Import Operations and ORA's Office of Enforcement to identify and take action on over 4,100 websites selling drug products in violation of U.S. law.

  During Operation Pangea V, OCI sent a representative to the INTERPOL command center in Lyon, France to provide hands-on assistance. In addition, warning letters were sent to Registries, Internet Service Providers (ISPs), and Domain Name Registrars (DNRs) informing them that these websites were selling products in violation of U.S. law. OCI is continuing to work with the U.S. Department of Justice and our foreign law enforcement counterparts to address the remaining websites that continue to offer unapproved or misbranded prescription medicines to U.S. consumers. OCI's participation with the IIWA

demonstrates FDA's commitment to protecting the public health by enforcing illegal activities for online sales of illicit drugs and other FDA regulated products.

- Internet Investigations - In April 2012, an OCI internet investigation, which relied on strong international law enforcement partnerships, resulted in the arrest and conviction of two Israeli citizens for selling counterfeit and misbranded drugs to United States citizens via the Internet. OCI agents identified over 9,000 separate drug shipments to the United States which generated over $1.4 million in gross proceeds.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
224201: Number of foreign and domestic high-risk human drug inspections. *(Output)*	FY 2012: 805 Target: 750 (Target Exceeded)	750	750	Maintain

Post Market Safety Oversight – Center Activities

Base Amount: $187,275,000 (BA: $77,389,000 / UF: $109,886,000)

Public Health Focus

CDER's post market safety functions aim to protect patients from injuries or deaths caused by unsafe, illegal, fraudulent, substandard, or improperly used drug products (both brand and generic). The following are key functions of the post market safety oversight subprogram:

- Surveillance, Risk Management, and Safe Use – Epidemiologists and safety evaluators collect and analyze drug use and adverse event data for both brand and generic drug products. If evaluators detect any new risks, FDA takes steps to inform the public and change how a drug is used or, if necessary, rescind approval. In-depth analyses of some of these concerns inform efforts to refine the communication of drug risks and benefits, and may highlight the need to develop or refine risk management programs such as Risk Evaluation and Mitigation Strategies (REMS). In some cases, FDA works with external stakeholders to encourage safe use. These targeted outreach efforts within the healthcare community aim to positively influence and support the safe and appropriate use of approved medications.
- Preventing Medical Errors – CDER avoids approving brand names that look or sound like the names of existing products to promote safe use of human drugs. CDER identifies and avoids approving brand names, labels, labeling, and packaging that might contribute to problems or confusion in prescribing,

dispensing, or administering drug products. CDER investigates the causes and contributing factors to reports of medical errors and, as needed, recommends revisions to the label, labeling, and/or packaging of these products to avert further error.

Public Health Outcome

CDER's post market safety activities exist to monitor the safety and efficacy of drugs that are currently available to consumers. CDER also aims to identify and communicate risks associated with approved drugs. The ongoing activities associated with post market safety allow FDA to discover risks associated with drug products that could not have been discovered during pre-market review. These efforts aim to protect patients from adverse events or improper use of drug products.

The Food and Drug Administration Amendments Act of 2007 (FDAAA) required FDA to establish an active surveillance system for monitoring drugs, using electronic data from healthcare information holders. FDAAA also mandated that the system access healthcare data for 100 million patients by July 2012. FDA's response to this requirement is the Sentinel Initiative, which successfully reached 100 million patients by December 2011, several months in advance of the required timeframe. The Sentinel Initiative presents significant public health benefits from expanding FDA surveillance of drugs available to consumers. This includes gaining access to large quantities of data that enhance FDA's ability to detect safety signals and act on post market safety issues.

Post Market Safety Oversight – Field Activities
Base Amount: $4,414,000 (BA: $4,414,000 / UF: $0)

Public Health Focus

ORA's public health focus under the Post Market Safety Oversight subprogram is to reduce adverse events such as injuries and deaths associated with unsafe, illegal, fraudulent, substandard, or improperly used products. ORA's inspection activities include inspections of Adverse Event Reporting and also Risk Evaluation Mitigation Strategies (REMS). The REMS inspection is an evaluation of compliance with the risk evaluation plan which was mandated by the Food and Drug Administration Amendments Act (FDAAA).

Public Health Outcome

ORA's activities to reduce adverse events involves the review of manufacturers' adverse event and complaint files during inspections to determine if the firm is submitting all adverse drug event reports to FDA in accordance with regulatory time frames. ORA also conducts follow-up inspections on adverse event reports when information from the manufacturer is needed to evaluate the risks involved. The final

activity involves investigations of reported errors and product recalls so that program managers can collect information and develop error reduction strategies with manufacturers and the medical community in order to better protect the public health.

FDA continues to perform operations in response to the 2008 incident in which heparin contaminated with over-sulfated chondroitin sulfate was associated to a number of deaths in the U.S. Heparin is a widely used anti-coagulant that is commonly used during surgical procedures and for those undergoing dialysis. In FY 2012, ORA issued the new Import Alert 55-03, "Detention Without Physical Examination (DWPE) of Different Forms of Heparin and Heparin - Related Products for Current Good Manufacturing Practices (cGMP) Issues" to implement detention without physical examination for those heparin suppliers implicated in the production of heparin contaminated with over-sulfated chondroitin sulfate, or for those manufacturing heparin outside of cGMPs. Currently over 30 firms are subject to DWPE under this import alert, which will help keep potentially contaminated product out of the U.S.

In FY 2012, FDA worked with CBP's Laboratory Science Service when that agency detected passengers returning to the United States with elevated gamma radiation readings. Interviews with passengers disclosed each had undergone a Positron Emission Tomography (PET) scan in recent weeks or months. ORA also worked with scientists at Los Alamos laboratories during the investigation to aid in identifying potential exposures to patients. ORA investigated the clinics where these patients had undergone the procedures and this led to identification of the manufacturer of the radiological drug products. Inspections were conducted identifying numerous current good manufacturing practice deficiencies and the potential breakthrough of detected isotopes from the columns used in producing these PET drugs. The inspection resulted in the firm recalling the drug product and removing the over-exposure potential from the public.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
292202: Number of people for whom FDA is able to evaluate product safety through miniature Sentinel*pilots. *(Outcome)*	FY 2012: 126 million Target: 100 million (Target Exceeded)	100 million	133 million	+ 33 million

Oversight of Drug Promotion – Center Activities

Base Amount: $22,342,000 (BA: $19,216,000 / UF: $3,126,000)

Public Health Focus

CDER is responsible for reviewing prescription drug information to ensure that healthcare professionals and consumers receive drug information that is truthful, balanced, and accurate. Prescription drug information available to physicians and consumers is critical for the safe and effective use of these products. CDER operates a comprehensive program of education, surveillance, and enforcement about drug advertising and promotion to achieve the goal of presenting truthful, balanced information to physicians and consumers.

Key functions of this subprogram include review of professional promotions (intended for healthcare professionals) and Direct-To-Consumer (DTC) advertisements (intended for consumers). CDER scrutinizes both types of drug promotions to ensure that information presented to the intended audiences is truthful and presents both the benefits and risks of drugs.

Public Health Outcome

Without suitable information regarding various drug products, consumers would face greater risks of inappropriate or unsafe use of drugs. By reviewing advertisements intended for medical professionals, CDER monitors the information disseminated to healthcare providers and requires messaging to be truthful, balanced, and not misleading. Medical professionals who are well-informed in part due to these advertising messages are better equipped to treat patients properly.

CDER regulates DTC advertisements to help ensure that consumers are well-informed about the drugs medical professionals prescribe for them. The promotional messages are required to be accurate and balanced so the public receives useful information about medical products. These efforts are intended to raise the public's awareness about drug information and mitigate risks that could occur due to a lack of awareness or misleading information.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
222302: Percentage of television advertisements requiring submission reviewed within 45 days. *(Output)*	FY 2012: Draft guidance issued (Target Met)	Issue draft guidance	Issue final guidance and establish a baseline	N/A

Information Technology Investments – Human Drugs Program Activities (Base Amount displayed as a non-add item: $88,924,687)

The ever increasing complexity of the human drug review process and the regulatory environment imposes new challenges for FDA and requires continuous streamlining of operations to fully leverage electronic information that has become available over the last decade. Digitization provides the means to take full advantage of the new opportunities in the 21st century. Digitization is a long-term effort with the aim to establish an integrated information environment that can transform business operations and drive efficiency. Digitization supports the following business objectives:

- Improve decision making via real-time information
- Standardize and simplify systems, processes and information
- Eliminate redundancy and improve consistency of information through automation and integration.

The following key initiatives are part of the digitization effort for CDER:

- Integrated Master Data Management is an effort to consolidate data from various disparate systems into a single repository of master data. This will enable data quality and consistency of master data across core business applications.
- The Facilities / Sites Inspection Management initiative focuses on providing an automated system for monitoring registration and listing compliance, for identifying manufacturers in the global supply chain, and improving reporting and analysis capabilities.
- Approved Drug Publishing is an effort to modernize current work processes and systems for the Orange Book. This involves consolidation of data sources related to drug information while automating the data collection processes to provide accurate and up to date information of available drugs in the marketplace.
- The Regulatory Review Management Solution (DARRTS) provides capabilities for managing new drug applications, abbreviated new drug applications, pediatrics, meetings, post-marketing requirements and commitments, as well as FDAAA provisions. Further enhancements to include biologics applications and cope with upcoming user fee tracking requirements for generic drugs, prescriptions drugs and biosimilars are needed. In addition, the DARRT System requires a fundamental technology refresh and redesign to meet the growing demands and improve overall efficiency of the system in support of a lean management approach and smarter regulation.
- Scientific Review: With the increase of standardized data submitted such as CDISC's Study Data Tabulation Model (SDTM), Standard for Exchange of Non-clinical Data (SEND), Analysis Data Model (Adam), as well as Health Level 7 Individual Case Safety Report (ICSR), there is an opportunity to analyze, compare and evaluate study data. The reviewers need to be provided with state-

of-the-art analysis tools that can support regulatory decision-making. The objective of this effort is to provide reviewers with access to scientific review tools in order to perform quantitative analysis of data using pre-defined templates and standardized reports.

- Adverse Event Management provides the solutions to enable safety investigators to analyze safety signals using state-of-the-art pharmacovigilance and surveillance tools ensuring the safety of marketed drugs after approval by monitoring adverse events and medication errors.
- The expansion of new user fee programs for biosimilars and generic drugs introduces a new level of complexity in terms of fee structures and payment volume. A sophisticated user fee management solution is required to enable fee establishment, collection and payment tracking.
- Efficient management of resources by consolidating financial information into a single core financial system and improving tracking capabilities of budgetary information is needed. Industry-proven financial tracking solutions will improve CDER's ability to efficiently manage and track its resources.
- Panorama is a strategic initiative to improve the management and administration of CDER's regulatory work processes in support of lean management by applying best-in-class portfolio management systems and tools that can be integrated with CDER's core business applications. The aim is to improve the effectiveness and efficiency of regulatory operations.

Funding History Table with FTE Totals

The following table displays funding and full time equivalent (FTE) staffing levels from FY 2010 through FY 2013, plus FY 2014 request.

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
FY 2010 Actual	$883,459,000	$462,243,000	$421,216,000	3,835
FY 2011 Actual	$949,645,000	$477,502,000	$472,143,000	4,061
FY 2012 Actual	$954,596,000	$477,623,000	$476,973,000	4,039
FY 2013 CR	$1,267,937,000	$480,735,000	$787,202,000	4,578
FY 2014 Request	$1,292,175,000	$465,950,000	$826,225,000	4,882

Summary of the Budget Request

The FY 2014 budget request for the Human Drugs Program is $1,292,175,000. This amount is an increase of $313,470,000 above the FY 2012 Enacted Level. The Center for Drug Evaluation and Research amount in this request is $1,097,091,000, supporting 3,917 FTE. The Field amount is $195,084,000, supporting 965 FTE.

The base funding for the Human Drugs Program is $978,705,000, which includes $838,694,000 for the Center for Drug Evaluation and Research activities and $140,011,000 for the Human Drugs Field activities.

Base funding allows the Human Drugs Program to meet its mission of ensuring that drugs available to the American public are safe and effective. This is accomplished by reviewing new drug applications to make sure that safety and efficacy are demonstrated – a process that draws on the expertise of a wide range of medical and health-services personnel – and then by monitoring drugs after they are released to the market for signs that could not have been detected in clinical trials. Manufacturers of drug products are periodically inspected to ensure that products are made to high standards. Even when safe and effective drugs are made to exacting standards, misuse (intentional or accidental) can still occur; CDER is working to improve the safe use of medical products by examining the communication of risks and benefits associated with those products. The mission of ensuring that safe and effective drug products are available to consumers is also accomplished by conducting inspections to ensure greater technical assistance and compliance in order to protect patients and ensure the safety of the medical products entering the drug supply chain.

Within the FY 2014 budget constraints, CDER will continue its top priorities to uphold the FDA mission of promoting and protecting the public health.

Budget Request Details

Pay Increase (Total Program: $2,099,000 / 0 FTE)

The request for $465,950,000 in total budget authority for the Human Drugs Program also reflects a pay increase of $2,099,000.The Center's portion is $1,528,000; the Field's portion is $571,000.

Adjustment to Base (Total Program: -$14,799,000 / -21 FTE)

The budget request for $465,950,000 in total budget authority for the Human Drugs Program also reflects a reduction to the base of -$14,799,000 for FY 2014. The Center's portion of this reduction is -$10,771,000 and -2 FTE; the Field's portion of this reduction is -$4,028,000 and -19 FTE.

New Drug Review

Center Activities
FY 2012 Enacted Base: $440,970,000 (BA: $119,256,000 / UF: $321,714,000)
FY 2014 Total Increase above Base: (+$44,751,000 / 97 FTE)
FY 2014 Increase above Base for Current Law User Fees (PDUFA): (+$28,607,000 / 38 FTE)
FY 2014 Increase above Base for User Fees (BsUFA): (+$15,304,000 / 59 FTE)

Medical Countermeasures: +$840,000 / (3 FTE non-add)

CDER will continue to coordinate with other parts of FDA on the Public Health and Security Action Teams (PHSAT) to foster support for MCM drug product review, and continue to assess Medical Countermeasure (MCM) safety and efficacy during public health emergencies.

Field Activities
FY 2012 Enacted Base: $35,684,000 (BA: $25,666,000 / UF: $10,018,000)
FY 2014 Total Increase above Base: (+$2,212000/ +5 FTE)
FY 2014 Increase above Base for Current Law User Fees (PDUFA): (+$890,000 / 0 FTE)
FY 2014 Increase above Base for Current Law User Fees (BsUFA): (+$1,322,000 / +5 FTE)

Generic Drug Review

Center Activities
FY 2012 Enacted Base: $87,936,000 (BA: $87,936,000)
FY 2014 Total Increase above Base: (+$170,828,000 / 359 FTE)
FY 2014 Increase above Base for Current Law User Fees (GDUFA): (+$170,828,000 / 359 FTE)

Field Activities
FY 2012 Enacted Base: $8,029,000 (BA: $8,029,000 / UF: $0)
FY 2014 Total Increase above Base: (+$16,692,000 / +54 FTE)
FY 2014 Increase above Base for Current Law User Fees (GDUFA): (+$16,692,000 / +54 FTE)

Drug Quality

Center Activities
FY 2012 Enacted Base: $100,171,000 (BA: $44,020,000 / UF: $56,151,000)
FY 2014 Total Increase above Base: (+$19,130,000 / 43 FTE)
FY 2014 Increase above Base for Current Law User Fees (PDUFA): (+$4,993,000 / 8 FTE)
FY 2014 Increase above Base for Current Law User Fees (GDUFA): (+$14,137,000 / 35 FTE)

Field Activities
FY 2012 Enacted Base: $91,884,000 (BA: $91,884,000 / UF: $0)
FY 2014 Total Increase above Base: (+$39,626,000 / +139 FTE)
FY 2014 Increase above Base for Current Law User Fees (GDUFA): (+$36,331,000 / +119 FTE)

FY 2014 Increase above Base for Proposed User Fees (Reinspection): (+$2,804,000 / +18 FTE)
FY 2014 Increase above Base for Proposed User Fees (International Courier): (+$491,000 / +2 FTE)

Post Market Safety Oversight

Center Activities
FY 2012 Enacted Base: $187,275,000 (BA: $77,389,000 / UF: $109,886,000)
FY 2014 Total Increase above FY 2012 Enacted: (+$32,653,000 / 60 FTE)
FY 2014 Increase above Base for Current Law User Fees (PDUFA): (+$9,771,000 / 10 FTE)
FY 2014 Increase above Base for Current Law User Fees (GDUFA): (+$22,510,000 / 50 FTE)
FY 2014 Increase above Base for Current Law User Fees (BsUFA): (+$372,000 / 0 FTE)

Field Activities
FY 2012 Enacted Base: $4,414,000 (BA: $4,414,000 / UF: $0)
FY 2014 Total Increase above Base: (+$0 / 0 FTE)

Oversight of Drug Promotion

Center Activities
FY 2012 Enacted Base: $22,342,000 (BA: $19,216,000 / UF: $3,126,000)
FY 2014 Total Decrease below FY 2012 Enacted: (+$278,000 / 0 FTE)
FY 2014 Increase above Base for Current Law User Fees (PDUFA): (+$278,000 / 0 FTE)

Human Drugs Program Activity Data (PAD)

CDER Workload and Outputs			
New Drug Review	**FY 2012 Actual**	**FY 2013 Estimate[1]**	**FY 2014 Request**
Workload – Submissions/Filings/Requests			
New Drug Applications/Biologic Licensing Applications (NDA/BLA)	122	126	136
Efficacy Supplements	135	147	161
Manufacturing Supplements	1,773	1,804	1,796
Commercial INDs (Drugs and Biologics) with Activity	6,046	6,195	6,326
Sponsor Requests: IND-Phase Formal Meetings	1,861	1,904	1,970
Sponsor Requests: Review of Special Study Protocols	276	250	226
Submissions of Promotional Materials	80,592	80,000	80,000
Outputs – Reviews/Approvals			
Reviews: Priority NDA/BLA	28	34	36
Reviews: Standard NDA/BLA	100	83	61
Approvals: Priority NDA/BLA	21	26	29
Approvals: Standard NDA/BLA	71	68	66
Mean time from Receipt to Approval: Priority NDA/BLAs (in months)	10.5	12.4	11.8
Mean time from Receipt to Approval: Standard NDA/BLAs (in months)	18.1	17.8	18.0
Median time from Receipt to Approval: Priority NDA/BLAs (in months)	6.0	6.0	6.0
Median Time from Receipt to Approval: Standard NDA/BLAs (in months)	10.1	10.0	10.0
Reviews: NDA Supplementals	3,336	3,584	3,833
Reviews: Clinical Pharmacology/ Bio-Pharmaceutic*	6,100	6,793	7,133
*FY 2012 actual data are currently not available for this category; the FY 2012 estimate has been included.			
Biologic Therapeutics Review			
Workload – Submissions/Filings/Requests			
Receipts: Commercial IND/IDE (Biologics Only)	78	76	74
Receipts: IND/IDE Amendments (Biologics Only)	14,711	13,588	12,605
Outputs – Reviews/Approvals			
Reviews: Total Original License Application (PLA/ELA/BLA)	9	8	8
Approvals: PLA/BLA	6	4	3
Reviews: License Supplement (PLA/ELA/BLA)	340	407	467
Generic Drug Review			
Workload – Submissions/Filings/Requests			
Receipts: Abbreviated New Drug Applications (ANDA)	1,103	850	850
Outputs – Reviews/Approvals			
Actions – ANDA	2,313	2,400	2,500
Approval Actions - ANDA (both Tentative and Full Approvals)**	619	604	625
Median Review Time from ANDA Receipt to Approval (months)	31.75	31.00	31.00
Actions - ANDA Supplementals (Labeling and Manufacturing)	4,453	5,000	5,500
**Assumes additional generic drug user fee resources beginning in FY 2013.			
Over-the-Counter Drug Review			
OTC Monographs Under Development***	28	28	28
OTC Monographs Published***	2	5	5
***Category includes Proposed Rules and Final Rules			
Best Pharmaceuticals for Children Act			
Labels Approved with New Pediatric Information	9	7	7
New Written Requests Issued	15	16	16
Pediatric Exclusivity Determinations made	10	7	7
Post Exclusivity Safety Report	9	9	9
Patient Safety			
Workload – Submissions/Filings/Requests			
Submissions: Adverse Event Reports	904,919	1,013,509	1,135,130
Electronic Submissions: % of Total Adverse Drug Reaction Reports	86%	90%	93%
Electronic Submissions: % of Serious/Unexpected Adverse Drug Reaction Reports	92%	94%	95%
Submissions: Drug Quality Reports	9,900	10,000	10,100
Outputs – Reviews/Approvals			
Safety reviews completed by Office of Surveillance & Epidemiology	2,323	3,000	3,000
Number of drugs with Risk Communications	195	225	250
Administrative/Management Support			
Workload			
Number of Advisory Committee Meetings	47	45	45
Number of FOI Requests	2,468	2,500	2,500
Number of FOI Requests Processed	2,905	2,700	2,700
Number of Citizen Petitions Submitted (excluding suitability petitions and OTC monograph-related petitions)	94	100	100
Number of Citizen Petitions Pending on Last Day of Fiscal year (excluding suitability petitions and OTC monograph-related petitions)	198	203	203
Number of Citizen Petitions Completed [1] (excluding suitability petitions and OTC monograph-related petitions)	117	95	95

[1] Spending authority has been adjusted pursuant to PL 112-175, Section 101(c) for the applicable user fee programs.

[1] Citizen Petitions completed may include petitions filed in prior years.

Combined Field Activities – ORA
Program Activity Data

Field Human Drugs Program Activity Data (PAD)

Field Human Drugs Program Workload and Outputs	FY 2012 Actual		FY 2013 [1] Estimate		FY 2014 Request	
FDA WORK						
DOMESTIC INSPECTIONS						
UNIQUE COUNT OF FDA DOMESTIC HUMAN DRUG ESTABLISHMENT INSPECTIONS	***2,120***		***1,856***		***1,856***	
Pre-Approval Inspections (NDA)	116		171		171	
Pre-Approval Inspections (ANDA)	107		216		216	
Bioresearch Monitoring Program Inspections	510		563		563	
Drug Processing (GMP) Program Inspections	1,134		591	2	591	
Compressed Medical Gas Manufacturers Inspections	280		295		295	
Adverse Drug Events Project Inspections	100		120		120	
OTC Monograph Project and Health Fraud Project Inspections	77		79		79	
Domestic Laboratory Samples Analyzed	1,450		1,450		1,450	
FOREIGN INSPECTIONS						
UNIQUE COUNT OF FDA FOREIGN HUMAN DRUG ESTABLISHMENT INSPECTIONS	***813***	1	***952***		***999***	3
Foreign Pre-Approval Inspections (NDA) incl PEPFAR	158		98		98	
Foreign Pre-Approval Inspections (ANDA) incl PEPFAR	108		83		83	
Foreign Bioresearch Monitoring Program Inspections incl PEPFAR	196		240		255	4
Foreign Drug Processing (GMP) Program Inspections	588		797	2	843	5
Foreign Adverse Drug Events Project Inspections	3		15		15	
TOTAL UNIQUE COUNT OF FDA HUMAN DRUG ESTABLISHMENT INSPECTIONS	***2,933***		***2,808***		***2,855***	
IMPORTS						
Import Field Exams/Tests	8,134		7,200		7,200	
Import Laboratory Samples Analyzed	493		490		490	
Import Physical Exam Subtotal	**8,627**		**7,690**		**7,690**	
Import Line Decisions	592,591		734,933		911,465	
Percent of Import Lines Physically Examined	1.46%		1.05%		0.84%	
STATE WORK						
UNIQUE COUNT OF STATE PARTNERSHIP HUMAN DRUG ESTABLISHMENT INSPECTIONS.	***100***		***100***		***100***	
State Partnership Inspections: Compressed Medical Gas Manufacturers Inspections	83		83		83	
State Partnership Inspections: GMP Inspections	17		17		17	
GRAND TOTAL HUMAN DRUG ESTABLISHMENT INSPECTIONS	***3,033***		***2,908***		***2,955***	

[1] Spending authority has been adjusted pursuant to PL 112-175, Section 101(c) for the applicable user fee programs.

[1] The FY 2012 actual unique count of foreign inspections includes 43 OIP inspections (2 for China and 41 for India).

[2] The FY 2013 planned mix of domestic versus foreign GMP inspections shifts quite a few more inspections into the foreign arena, with a corresponding decrease to domestic GMP inspections in comparison to the FY 2012 actuals,

but the overall coverage is not changing. This is being done to achieve greater parity of the foreign versus domestic inspections and thus level out the inspection coverage.

[3] For investigators hired with FY 2014 BA funding received through the Office of International Programs (OIP) for the China Import Safety Initiative, the full performance year is FY 2016. During the full performance year (FY 2016), the FY 2014 funding increase for inspections will allow OIP to conduct an additional 120 foreign human drug safety inspections. Please also see the FDA Headquarters /OIP narrative for further information.

[4] For ORA investigators hired with FY 2011 enacted increases, the full performance year is FY 2014 for foreign generic drug bioequivalence laboratory inspections. During the full performance year (FY 2014), the FY 2011 funding increases for inspections ORA to conduct an additional 15 foreign bioresearch monitoring inspections.

[5] For ORA investigators hired with FY 2011 enacted increases, the full performance year is FY 2014. During the full performance year (FY 2014), the FY 2011 funding increases for inspections will allow ORA to conduct an additional 46 foreign GMP surveillance inspections.

Office of Orphan Products Development[30]

The following table displays funding levels for FY 2012 through FY 2014.

	FY 2012 Actual	FY 2013 Estimate	FY 2014 Request	FY 2014 +/- FY 2012
Program Level	$23,636,200	$23,598,688	$23,598,688	$37,512
Orphan Product Grants[a]	$14,013,200	$14,035,060	$14,035,060	$21,860
Pediatric Consortia Grants[b]	$3,000,000	$3,000,000	$3,000,000	0
Program Administration[c,d]	$6,623,000	$6,563,628	$6,563,628	-$59,372

[a]Orphan Product Grants are part of the aggregate amount of budget authority contained in the CDER budget line item of the All Purpose Tables.
[b]Pediatric Device Consortia Grants are part of the aggregate amount of budget authority contained in the CDRH budget line item of the All Purpose Tables.
[c]Program Administration is part of the aggregate amount of budget authority contained in the Other Activities budget line item of the All Purpose Tables.
[d] FY 2012 included a supplemental increase of $1,680,000 to implement FDAAA, which supported Orphan Product Grants. FY 2013 and FY 2014 include a supplemental increase of $1,200,000 to implement FDAAA and also will support Orphan Product Grants.

The FDA Office of Orphan Products Development operates under the following legal authorities:

Federal Food, Drug and Cosmetic Act (21 U.S.C. 321-399).
Orphan Drug Regulations (21 CFR 316)
Safe Medical Device Act of 1990 (as amended) (21 U.S.C. 351-353, 360, 360c-360j, 371-375, 379, 379e, 381)
Humanitarian Use Device and Humanitarian Device Exemption Regulations: (21 CFR 814 Subpart H)

[30] The Office of Orphan Products Development is shown for illustrative purposes and is not contained as a separate line item in the All Purpose Tables.

PHS Act (42 U.S.C. 241). Section 301
Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331 et seq.)

Allocation Method: Direct Federal/Intramural; Grants.

Program Description and Accomplishments

Since its inception in 1982, the public health programs of the Office of Orphan Products Development (OOPD) promoted and advanced the development of innovative products (drugs, biologics, medical devices, and medical foods) that demonstrate promise for the diagnosis and/or treatment of rare diseases or conditions. These are products necessary to treat a patient population that otherwise would be considered too small for profitable research, development, and marketing. OOPD has five public health sub-program activities noted below. These programs directly support the HHS priority to accelerate scientific advances in lifesaving cures and quality health outcomes. Further, OOPD activities support FDA's strategic public health goals by enhancing the process of developing promising new products into safe, effective, and accessible treatments for patients.

Orphan Product Grants Activity

Public Health Focus

Orphan product grants are a proven method of successfully fostering and encouraging the development of new safe and effective medical products for rare diseases/conditions. These grants support new and continuing extramural research projects that test the safety and efficacy of promising new drugs, biologics, devices, and medical foods through human clinical trials.

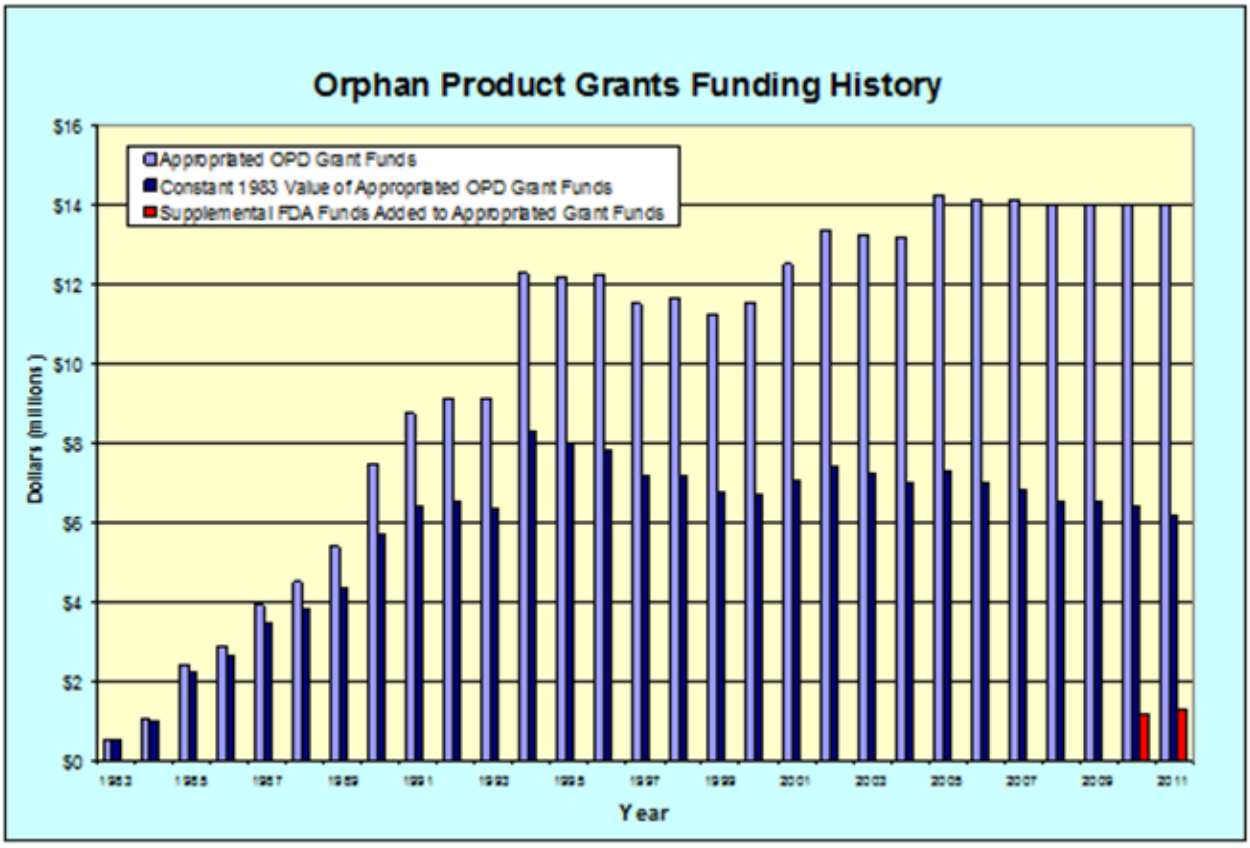
Grants are a very modest investment to help ensure that product development occurs in a timely manner. Funding clinical trials for promising orphan products continues to reap significant public health benefits to society.[31] However, FDA grant funds are covering less and less of the total cost for conducting clinical trials, which continue to increase far faster than the rate of medical inflation. For example, pediatric study costs increased eight-fold between 2000 and 2006 as a result of more complexity.[32] In addition, the design of clinical trials is even more complicated for rare diseases because there are fewer available patients.

[31] Johnston SC , Rootenberg JD, Katrak S, Smith WS, Elkins JS. "The impact of an NIH program of clinical trials on public health and costs." *The Lancet*, April 22, 2006, Vol. 367, pp. 1319-1327.

[32] Kaitin KI, editor. Pediatric study costs increased 8–fold since 2000 as complexity level grew. *Tufts Center for the Study of Drug Development Impact Report* 2007 Mar/Apr;9(2)

Because of the increased costs of clinical trials, FDA increased the maximum grant award amount and maximum number of grant years. As a result of no increases in the amount of appropriated grant funds, the amount of grant funds appropriated was supplemented with $1.20 million, $1.28 million and $1.68 million in FY 2010, FY 2011 and FY 2012 respectively from Program Administration to support three additional grants each year.

The following chart displays the orphan product grants funding history from FY 1983 to FY 2011.



Public Health Outcome and Accomplishments

Forty-eight (48) studies that received development support from the Orphan Products Grants Program have led to the approval of 44 different products by the FDA for marketing for 42 different indications. These include treatments for Dupuytren's Disease (2010) and scorpion antivenom (2011). In FY 2012, OOPD funded 16 new grants (out of 125 grant applications) and provided funding or continued support for approximately 55 other ongoing clinical study projects. Research projects that recently were awarded new grants include studies for the treatment of High-Risk Sickle Cell Anemia, Type I Hyperlipoproteinem, Cutaneous T-Cell Lymphoma, and Pseudoxanthoma Elasticum.

Orphan Drug Designation Activity

Public Health Focus

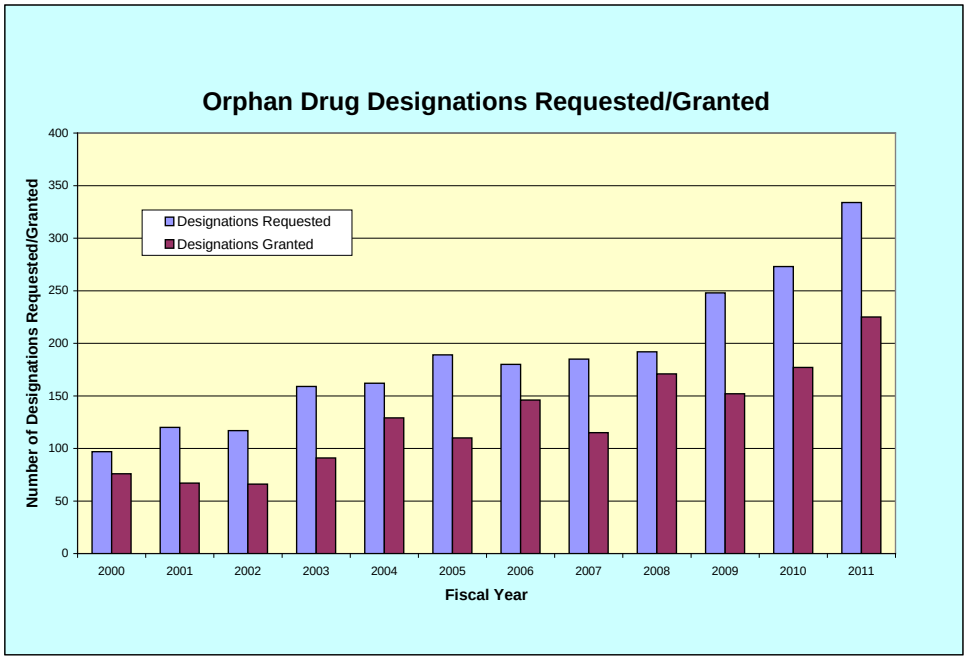
There are an estimated 7,000 rare diseases, with a public health impact directly affecting more than 25 million (and many millions of family members more) in the U.S. Between 85 and 90 percent of these are serious or life-threatening. OOPD administers the major provisions of the Orphan Drug Act (ODA) of 1983 by which Congress sought to provide incentives to promote the development of drugs (including biological products) for the treatment of rare diseases or disorders that affect fewer than 200,000 persons in the U.S. OOPD evaluates applications for orphan drug designations from sponsors who are developing drugs to treat rare diseases. The developer of a designated orphan drug that is approved by FDA for marketing is eligible for seven years of market exclusivity for a specific indication if they meet certain criteria.

Public Health Outcome and Accomplishments

Of the 2,682 orphan drug designations issued by OOPD since 1983, over 400 have resulted in marketing approval with orphan exclusivity. In contrast, the decade prior to 1983 saw fewer than ten such products come to market. During FY 2012, OOPD received 259 new applications for orphan drug designation, These included potential treatments for many kinds of cancers, sickle cell disease, cystic fibrosis, and pediatric multiple sclerosis. OOPD designated 179 orphan drugs in FY 2012.

The number of requests for orphan designation has more than doubled since 2000. Not only are the requests increasing, but the complexity of the science of potential orphan drugs is increasing. There are many more entrepreneurial ideas and concepts being considered in the areas of pharmaco-genomics and individualized medicine that challenge FDA reviewers. In FY 2012, 27.3 percent of all the new molecular entities (NME) approved by the FDA were orphan designated drugs and biologics.

The following chart displays orphan drug designations requested and granted from 2000 to 2011.



FDA approved 20 orphan designated drugs for marketing in FY 2012. One recent example is the marketing approval in January 2012 of Kalydeco for the treatment of cystic fibrosis in patients 6 years of age and older who have a G551D mutation in the CFTR gene. Cystic fibrosis affects 30,000 people in the United States. This drug received orphan status in December 2006.

Humanitarian Use Device Designation Activity

Public Health Focus

The purpose of the Humanitarian Use Device (HUD) program is to encourage the discovery, development, and use of medical devices intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year.

For diseases or conditions affecting small patient populations, a device manufacturer's research and development costs can exceed its market returns. FDA published a regulation in 1996 to carry out provisions of the Safe Medical Devices Act of 1990 to provide an incentive for the development of devices for use in the treatment or diagnosis of diseases affecting these populations.

Devices that receive a HUD designation may be eligible for marketing approval under an humanitarian device exemption (HDE) if among other criteria, the device will not

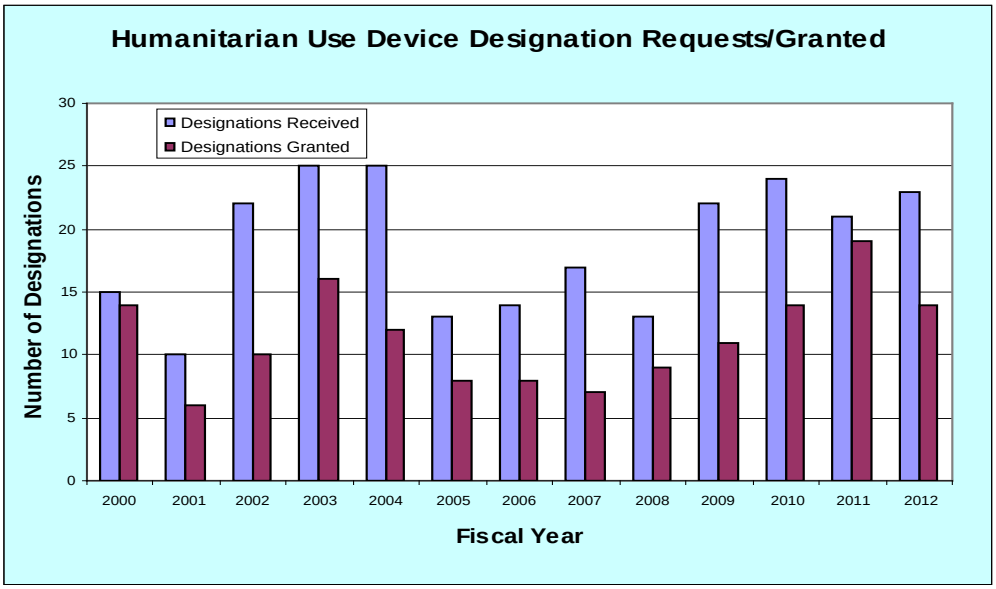
expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health from use of the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment. Since 1990, 56 HUD devices have been approved for marketing.

The Pediatric Medical Device Safety and Improvement Act of 2007 (Public Law 110-85) allows HDE-approved devices intended for use in pediatric patients or in a pediatric subpopulation (device would be intended for pediatrics and adults) and approved on or after September 27, 2007, to be sold for profit. Likewise, the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012 amended section 520(m) to further expand the criteria that allow HDE approved devices to be sold for profit. Currently, three HDEs have received approved to make profit and other sponsors have submitted requests to qualify for the exemption from the profit prohibition.

Public Health Outcome and Accomplishment

In FY 2012, OOPD received 23 new HUD applications and designated 8 devices. An additional 6 devices were designated based on HUD applications originally submitted in prior years for a total of 14 HUD devices designated in FY 2012. In FY 2012, 3 devices received an HDE approval from CDRH.

The following chart displays Humanitarian Use Device designations requested and granted from 2000 to 2012.



Performance Measures – Orphan Drug and HUD Designations

The following table lists Office of Orphan Products Development performance measures.

Measure	Year and Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
293201: The total number of *decisions* on applications for promising orphan drug and humanitarian use device designations.	FY 2011: 451 Target: 312 (Target Exceeded)	425	425	Maintain
293202: The cumulative number of proposed medical devices provided development assistance by all the Pediatric Device Consortia.	FY 2011: 90 Target: 90 (Target Met)	100	225	+125

Pediatric Device Consortia Grants Activity

Public Health Focus

There exists a great public health need for medical devices designed specifically for children. The development of pediatric medical devices currently lags five to ten years behind those for adults due to the lack of commercial incentives for pediatric medical device development. Children differ from adults in terms of their size, growth, development, and body chemistry, adding to the challenges of pediatric device development. Such needs include the de novo development of pediatric medical devices, as well as the specific adaptation of existing adult devices for children. Thus, as part of the 2007 FDAAA legislation, Congress passed the Pediatric Medical Device Safety and Improvement Act of 2007. Section 305 of this Act mandates demonstration grants for improving pediatric device availability, to be administered for the creation of pediatric device development consortia. The demonstration grants are not limited to addressing diseases or conditions that are considered to be rare.

As a result of the Act and subsequent appropriations, the FDA Pediatric Device Consortia Grant Program was established. Its goal is to support the development of nonprofit consortia designed to stimulate projects which will promote pediatric device development.

Public Health Outcome and Accomplishments

So far, five Pediatric Device Consortia have been established under this program. The five consortia are located in Boston, San Francisco, Ann Arbor (MI), Palo Alto (CA), and Atlanta. Collectively, they have provided development assistance to more than 200 medical device projects.

Outreach Activity

Public Health Focus

OOPD participates in significant outreach activities by

- providing information on approved therapies for rare diseases for the patient community and advocacy groups
- speaking at meetings and conferences on the FDA approval processes, the Orphan Products Grants Program, and the science of developing therapeutic products for rare diseases/conditions
- assisting patients and advocacy groups on issues of concern related to rare diseases and orphan products, such as drug shortages.

Public Health Outcome and Accomplishments

In FY 2012**,** OOPD received more than 80 invitations to speak/participate at orphan drug stakeholder meetings (includes conferences). OOPD made presentations and participated in 55 of these meetings, often to explain how orphan drugs and humanitarian devices could be developed with ODA incentives and HDE provisions. At these meetings, the missions of OOPD and FDA were explained, and the questions and concerns from stakeholders were addressed. Examples of public health related OOPD outreach activities in FY 2012 include conducting training courses for researchers and reviewers, workshops for drug and device sponsors, and presentations to national and international rare disease patient groups.

Five Year Funding Table

The following table displays funding levels from FY 2010 through FY 2014 for the Office of Orphan Products.

Fiscal Year	Program Level
FY 2010 Actual	$22,785,290
FY 2011 Actual	$22,175,488
FY 2012 Actual	$23,636,200
FY 2013 CR	$23,598,688
FY 2014 Request	$23,598,688

Budget Overview and Supported Activities

The FY 2014 budget request for the Office of Orphan Products Development is $23,598,688. This amount is a reduction of $37,512 below FY 2012. The funding would support eight Orphan Product Grants to support research on clinical trial safety and efficacy of new drugs, biologics, devices and medical foods and four Pediatric

Device Consortia Grants to support pediatric device development will be awarded, as well as program administration.

Office of Orphan Products Development
Program Activity Data (PAD)

PROGRAM WORKLOAD AND OUTPUTS	FY 2011 Actual	FY 2012 Actual	FY 2013 Estimate	FY 2014 Request
Grants Programs				
New Orphan Product Grants Awarded	14	16	8	8
Total Pediatric Consortia Grants (new and continuations)	5	5	4	4
Orphan drug requests, designations, and market approvals				
New Designation Requests	334	259	300	300
Designations	225	179	200	200
Market Approvals	25	20	20	20
HUD Requests and Designations				
New Designation Requests	21	23	25	25
Designations	19	14	12	12

Biologics Program

The following table displays the funding and full time equivalent (FTE) staffing levels for FY 2012 through FY 2014.

FDA Program Resources Table

(Dollars in Thousands)

	FY 2012		FY 2013[1]	FY 2014	+/- FY
	Enacted	Actuals	CR	Request	2012
Program Level	**$329,136**	**$308,620**	**$334,469**	**$337,946**	**+$8,810**
Center	$283,904	$265,946	$288,858	$292,417	+$8,513
FTE	1,055	1,089	1,108	1,115	+26
Field	$45,232	$42,674	$45,611	$45,529	+$297
FTE	239	230	234	241	+11
Program Level FTE	**1,294**	**1,319**	**1,342**	**1,356**	**+37**
Budget Authority	**$212,224**	**$212,298**	**$213,523**	**$210,759**	**-$1,465**
Center	$171,711	$171,788	$172,762	$170,575	-$1,136
Field	$40,513	$40,510	$40,761	$40,184	-$329
Budget Authority FTE	**905**	**876**	**896**	**892**	**16**
Center	672	652	668	661	9
Field	233	224	228	231	7
User Fees	**$116,912**	**$96,322**	**$120,946**	**$127,187**	**+$10,275**
Center PDUFA	$101,010	$85,927	$104,071	$109,993	+$8,983
FTE	355	400	400	408	+8
Field PDUFA	$4,207	$1,736	$4,335	$4,581	+$374
FTE	5	6	6	6	+0
Center MDUFMA	$11,183	$8,231	$11,251	$10,301	-$882
FTE	28	37	37	40	+3
Field MDUFMA	$512	$428	$515	$192	-$320
FTE	1	0	0	1	1
Center Generic Drugs	0	0	0	$774	+$774
FTE	0	0	0	3	+3
Field Generic Drugs	0	0	0	0	0
FTE	0	0	0	0	0
Center Biosimilar User Fee	0	0	$774	$774	+$774
FTE	0	0	3	3	+3
Field Biosimilar User Fee	0	0	0	0	0
FTE	0	0	0	0	0
Field Medical Products Reinspection User Fee[2]	0	0	0	$572	+$572
FTE	0	0	0	3	+3
User Fees FTE	**389**	**443**	**446**	**464**	**21**

[1]Spending authority has been adjusted pursuant to PL 112-175, Section 101(c) for the applicable user fee programs.
[2] Proposed user fee.

FDA's Biologics Program operates under the following legal authorities:

Public Health Service Act
Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 321-399)
Medical Device Amendments of 1976*
Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 201)
Safe Medical Devices Act of 1990*
Medical Device Amendments of 1992*
Food and Drug Administration Modernization Act of 1997*
Medical Device User Fee and Modernization Act of 2002*
Public Health Security and Bioterrorism Preparedness Response Act of 2002*
Project BioShield Act of 2004 (21 U.S.C. 360bbb-3)
Medical Device User Fee Stabilization Act of 2005*
Food and Drug Administration Amendments Act of 2007*
Biologics Price Competition and Innovation Act of 2009*
Patient Protection **and** Affordable Care **Act of 2010***
Food and Drug Administration Safety and Innovation Act of 2012*

Allocation Method: Direct Federal/Intramural

Program Description and Accomplishments

The FDA Biologics Program began in 1902 with the passage of the Biologics Control Act. This act established the authority to regulate biological products and ensure their safety for the American public. The program began in the Department of Treasury's Hygienic Laboratory and later became part of the National Institutes of Health (NIH) in 1930. In 1972, the Biologics Program was transferred from NIH to FDA and became the Bureau of Biologics. In 1988, the bureau became the Center for Biologics Evaluation and Research (CBER) which, with the Office of Regulatory Affairs' (ORA) Field Biologics Program, comprises the FDA Biologics Program.

The Biologics Program (CBER and ORA) protects and promotes public health by ensuring the safety, purity, potency and effectiveness of biological products for the prevention, diagnosis, and treatment of a wide variety of human diseases, conditions or injuries. Most products that CBER regulates are complex biological entities including live agents and cells that involve novel and cutting-edge technologies and evolving science. The Biologics Program also protects public health against the threat of

* Authorities under this act do not appear in sequence in the United States Code. The authorities are codified as amended in scattered sections of 21 U.S.C.

emerging infectious diseases, neglected tropical diseases, and potential bioterrorism agents.

CBER ensures the safety, purity, potency and effectiveness of biological products, including vaccines and allergenic products, blood and blood products, cells, tissues, and gene therapies for the prevention, diagnosis, and treatment of a wide variety of human diseases, conditions or injuries. Most products that CBER regulates are complex biological entities including live agents and cells that involve novel and cutting-edge technologies and evolving science.

The ORA Field Biologics Program supports the Biologics Program by:

- Assessing industry compliance with current good manufacturing practice and other applicable FDA regulations and recommending regulatory actions to CBER
- Conducting risk-based inspections of domestic and foreign establishments to determine compliance with applicable requirements
- Performing entry review of imported products
- Assuring rights of human subjects participating in clinical trials are protected through proper oversight
- Reviewing data submitted to FDA and used in support of applications to ensure it is valid and reliable
- Monitoring recalls of violative products
- Investigating complaints

Regulatory responsibilities for the Biologics Program are executed in three subprograms:

- Vaccines Premarket Review and Postmarket Safety
- Cells, Tissues and Gene Therapy Premarket Review and Postmarket Safety
- Blood and Blood Products Premarket Review and Postmarket Safety.

Vaccines Premarket Review and Postmarket Safety – Center Activities
Base Amount: $135,148,740 (BA: $75,552,840 / UF: $59,596,000)

Public Health Focus

The Vaccines Premarket Review and Postmarket Safety subprogram facilitates the development and approval of safe and effective vaccines, allergenic extracts and related biologic products. CBER promotes public health by evaluating the safety and effectiveness of therapeutic and preventive vaccines for infectious diseases and related biological products and by taking appropriate regulatory actions on investigational new drug applications (INDs) and biologics license applications (BLAs).

CBER plans and conducts mission-oriented research related to developing, manufacturing, and evaluating safe and effective vaccines and related biological products. CBER also develops guidance, policies, and procedures and conducts outreach to consumers, health care providers and the regulated industry.

Public Health Outcome

CBER's expertise in the areas of research, vaccine manufacturing, and regulatory science facilitates the availability of safe and effective vaccines in the United States and in the international community. In February 2012, CBER obtained redesignation as a World Health Organization (WHO) Collaborating Center for Biological Standardization in coordination with the Pan American Health Organization and WHO. CBER conducted regulatory science research and shared results with other WHO Collaborating Centers and the global community to advance product development (for influenza and other vaccines), improve methodologies for strain selection, and enhance safety monitoring post-vaccination.

CBER also served as reference National Regulatory Authority for eight prequalified vaccines, which include several influenza virus vaccines as well as rotavirus and pneumococcal vaccines. The vaccine prequalification program is a service provided by WHO to United Nations (UN) agencies that purchase vaccines, providing independent guidance and advice to the UN on the quality, safety, and efficacy of vaccines being considered for purchase. The service helps to ensure that each vaccine under consideration is suitable for target populations and continues to comply with established standards of quality.

CBER coordinates and participates in public workshops on emerging scientific and regulatory issues. These workshops bring together outside independent technical experts from various scientific disciplines to assist FDA in analyzing detailed data and understanding its public health significance. Furthermore, CBER develops and issues guidance to the vaccine industry to communicate scientific and regulatory requirements, recommendations and frameworks for the development of vaccines. CBER is actively engaged in exchanges with industry about regulatory pathways to licensure to facilitate the development and availability of vaccine candidates produced using new technologies. CBER also assists manufacturers by helping to determine the potency of vaccines, examining the genetic makeup of potential high growth viruses, and developing assays to determine the presence of contaminating infectious agents in cell cultures.

CBER also works to optimize the vaccine review and licensing process. CBER's regulatory efforts resulted in the availability of many important safe and effective vaccines in recent years such as Prevnar 13, Zostavax, Ixiaro, Menhibrix, Adenovirus Type 4 and Type 7, Menactra and the approval of new influenza vaccines, increasing the available supply of seasonal influenza vaccines to thirteen for the United States. Recent noteworthy approvals include FluMist Quadrivalent, Fluarix Quadrivalent,

Flucelvax, and Flublok. FluMist and Fluarix Quadrivalent are the first seasonal influenza vaccines to contain four strains of the influenza virus (two A and two B strains), which increases the likelihood for adequate protection against circulating influenza virus strains.

Flucelvax is the first seasonal influenza vaccine licensed in the United States that is manufactured using cell culture technology; specifically, mammalian cells are used instead of fertilized chicken eggs. Advantages of this technology include an adequate supply of previously tested and characterized cells for use in influenza vaccine production and the potential for a faster start-up of the vaccine manufacturing process in the event of a pandemic. Flublok is the first influenza vaccine made using an insect virus (baculovirus) expression system and recombinant DNA technology. The availability of FluBlok represents a technological advance in the manufacturing of an influenza vaccine. The new technology is not dependent on an egg supply or on availability of the influenza virus, thereby; it also offers the potential for faster start-up of the vaccine manufacturing process in the event of a pandemic.

CBER conducts a robust post-marketing program after a vaccine is approved and evaluates the results of clinical studies that manufacturers conduct as post-marketing commitments or requirements to further evaluate the safety and/or effectiveness of vaccines. CBER also collaborates with federal partners to perform safety surveillance in ongoing activities and in response to emerging safety signals. CBER works with other federal and international partners to expand and improve post-marketing surveillance capacities and strategies for monitoring the safety of influenza vaccines and other preventive vaccines in diverse populations.

CBER continually monitors vaccines following licensure, and reviews, interprets, and analyzes adverse event reports collected through jointly operated the Vaccine Adverse Event Reporting System (VAERS) database with the Centers for Disease Control and Prevention (CDC), to ensure the safety of vaccines used in the general population. In addition, CBER collaborates with CDC to perform studies and rapid-cycle analyses through CDC's Vaccine Safety Datalink, an active surveillance system with eight health maintenance organizations. CBER reviews pharmacovigilance plans for original BLAs and supplements to strengthen manufacturers' plans for monitoring safety after licensure. Additionally, CBER participates in the Global Regulatory Utilization of Vaccine Safety and Surveillance Initiative launched in April 2012, to strengthen global vaccine pharmacovigilance capacity.

CBER continues to develop the Post-Licensure Rapid Immunization Safety Monitoring (PRISM) program, the largest electronic real-time active surveillance system for vaccine safety in the United States. Studies from PRISM initiated in FY 2012 include safety signals for Rotavirus and Human Papillomavirus vaccine; febrile seizures after influenza and other concomitantly administered vaccines; and pregnancy outcomes after influenza vaccines. The first project on Health Outcomes of Interest for Vaccine Adverse Events was also published.

CBER issued the final rule amending the Sterility Test Requirements for Biological Products which was effective on June 4, 2012. The rule encourages the adoption of innovative methods for sterility testing of biological products, providing more flexibility while assuring comparable or better sensitivity and specificity. CBER also developed a communication plan and editorial, "Enabling Innovation for Biological Product Safety," on the FDA Blog to highlight this important rule focused on encouraging innovation.

Vaccines Premarket Review and Postmarket Safety – Field Activities
Base Amount: $5,842,000 (BA: $4,383,000 / UF: $1,459,000)

Public Health Focus
ORA supports the Biologics Program in ensuring the safety, purity, potency and effectiveness of vaccines and allergenic products for the prevention and treatment of human diseases or conditions and helps to defend the public against the threats of emerging infectious diseases and bioterrorism.

Public Health Outcome

ORA accomplishes a majority of its regulatory and public health responsibilities by conducting inspections both domestically and abroad, by performing entry review on imported products, by investigating and building compliance cases, and by monitoring recalls.

Throughout FY 2012, ORA field investigators conducted surveillance inspections of vaccine manufacturers to assess manufacturing operations and document violations of current good manufacturing practice requirements. Efforts such as these continue to serve the American public health by ensuring that the vaccine industry continuously reviews the quality standards of their manufacturing operations to ensure the safety of vaccines on the US market.

In July 2012, ORA inspections of two foreign bacterial and viral vaccine manufacturers revealed corporate wide deviations from current Good Manufacturing Practice (cGMP) resulting in the issuance of a Warning Letter to the manufacturer's corporate headquarters. During one of the inspections, ORA investigators with participation from CBER, found that the firm's re-validation of the sterility test method failed to detect yeast and mold that was detected in the firm's aseptic processing area. The results of these inspections not only served to protect the health of the American public, but ensured corporate management addresses corrective actions to their manufacturing operations from a global perspective.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
233201: Complete review and action on standard original PDUFA NDA/BLA submissions within 10 months of receipt. *(Output)*	FY 2011: 100% Target: 90% (Target Exceeded)	90%	NA *	NA
233202: Complete review and action on priority original PDUFA NDA/BLA submissions within 6 months of receipt. *(Output)*	FY 2011: NA (No Applications Received)	90%	NA *	NA
233207: Review and act on standard New Molecular Entity (NME) NDA and original BLA submissions within 10 months of the 60 day filing date. *(Output)*	NA New Goal *	NA	90%	NA
233208: Review and act on priority NME NDA and original BLA submissions within 6 months of the 60 day filing date. *(Output)*	NA New Goal *	NA	90%	NA
233209: Review and act on standard non-NME original NDA submissions within 10 months of receipt. *(Output)*	NA New Goal *	NA	90%	NA
233210: Review and act on priority non-NME original NDA submissions within 6 months of receipt. *(Output)*	NA New Goal *	NA	90%	NA
233203: Complete review and action on standard PDUFA efficacy supplements within 10 months of receipt. *(Output)*	FY 2011: 100% Target: 90% (Target Exceeded)	90%	90%	Maintain
234101: Increase manufacturing diversity and capacity for influenza vaccine production. *(Output)*	FY 2012: Evaluated three new methods for the determination of influenza vaccine potency and measured the potency of inactivated influenza vaccines from several manufacturers. (Target Met)	Evaluate and compare new methods to determine the potency of influenza vaccines.	Continue evaluation of new methods to produce high-yield influenza vaccine reference strains.	NA

Cells, Tissues and Gene Therapy Premarket Review and Postmarket Safety – Center Activities

Base Amount: $53,837,190 (BA: $32,625,090/ UF: $21,212,100)

Public Health Focus

The Cells, Tissues and Gene Therapy Premarket Review and Postmarket Safety subprogram facilitates the safe and effective development of novel biologic products by issuing guidance and regulations, developing policy, taking appropriate regulatory actions on IND and BLA submissions, and providing education and outreach activities to the regulated community. Regulated products in this subprogram include but are not limited to: Human Cells, Tissues and Cellular and Tissue-Based Products (HCT/Ps); gene therapies; tumor vaccines; immunotherapy; xenotransplantation; combination products such as bioengineered tissues and devices with a cellular component and selected devices for the manufacture and/or delivery of a biologic product at the point of care.

In 2009, President Obama issued Executive Order 13505, "*Removing Barriers to Responsible Scientific Research Involving Human Stem Cells,"* which resulted in an increase in research and development in the use of human stem cells for therapeutic purposes. CBER needs to stay abreast of scientific developments in this rapidly developing area so that policies reflect the most current scientific knowledge. CBER interacts with industry and other stakeholders to better anticipate scientific and regulatory challenges that may arise in the review of investigational and licensing applications for novel stem cell products. CBER and NIH developed a partnership to identify key needs that can be addressed jointly with the goal of moving pluripotent stem cell therapies into the clinic. Further efforts are ongoing, and the importance of stem cell research to the nation was recognized by its inclusion in the Presidential Initiative on the National Bioeconomy Blueprint, issued in April 2012.

Public Health Outcome

Gene therapy is a novel and rapidly evolving product class that requires early scientific and regulatory interaction and guidance. While gene therapy products have the potential to treat illness and cure disease, they also have the potential to result in serious adverse events, such as inadvertent germ line transmission of infectious disease and excessive cell growth and malignancy. CBER works closely with NIH, academia, industry, patient advocacy groups and various professional associations as an effective means to address potential risks and benefits of innovative gene therapy products.

CBER continues to promote the development of cell and gene therapy products by issuing regulatory guidance documents for industry. CBER implemented a risk-based approach for ensuring HCT/P safety by developing new guidance to convey current recommendations for complying with the HCT/P regulations and meeting regularly to

address tissue safety and policy issues through the interdisciplinary CBER Tissue Safety and Tissue Policy Teams. In December 2011, CBER and the Center for Devices and Radiological Health (CDRH) issued guidance for products intended to repair or replace knee cartilage and "Guidance for Industry: Current Good Tissue Practice (CGTP) and Additional Requirements for Manufacturers of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)".

CBER is expanding regulatory research capabilities by identifying, developing, and evaluating methods to characterize products that will be predictive of clinical function. Additionally, CBER scientists are studying the causes and mechanisms that may underlie adverse events in cell and gene therapies, addressing the regulatory and scientific challenges in the characterization of these products, and developing animal models to assess safety.

CBER also conducts webinars for industry, including collaboration with the California Institute for Regenerative Medicine to develop a May 2012 Focus on the Eye webinar. This provided an overview of FDA regulations for cellular and gene therapies, including combination products, for retinal disorders, discussed issues and challenges of taking an ophthalmic product through to an IND application, and considered clinical trial designs for retinal disorders. In collaboration with NIH, in April 2012, CBER held a second in a series workshop on pluripotent stem cells that discussed non-clinical studies with stem cells.

CBER also developed a webinar series that covered IND basics, sponsor meetings and chemistry, manufacturing and control information for cell and gene therapy INDs, and discussion of preclinical and clinical trial design issues. Additionally, in February 2012, CBER jointly organized the 15th U.S. – Japan Cellular and Gene Therapy conference under the U.S. - Japan Cooperative Activity on Cutting Edge Biomedical Research program. This program has enhanced cooperation between the U.S. and Japan in the fields of recombinant DNA and cellular therapy.

CBER approved three cord blood products in the past year. In November 2011, HEMACORD became the first approved BLA cord blood product for use in hematopoietic stem cell transplantation in patients with disorders affecting the hematopoietic (blood forming) system. CBER subsequently approved HPC, Cord Blood and DUCORD, two additional BLAs for use in hematopoietic stem cell transplantation procedures.

In March 2012, CBER approved GINTUIT (Allogeneic Cultured Keratinocytes and Fibroblasts in Bovine Collagen) for topical (non-submerged) application to a surgically created vascular wound bed in the treatment of mucogingival conditions in adults. Gintuit is not intended to provide root coverage.

Cells, Tissues and Gene Therapy Premarket Review and Postmarket Safety – Field Activities
Base Amount: $11,938,000 (BA: $10,756,000 / UF: $1,182,000)

Public Health Focus

ORA supports the Biologics Program in ensuring the safety, purity, potency and effectiveness of cells, tissues, and gene therapies for the treatment of human diseases, conditions, or injuries and helps to defend the public against the threats of emerging infectious diseases and bioterrorism. In monitoring establishments related to HCT/Ps, the focus is on an establishment's ability to manufacture HCT/Ps in accordance with regulations to prevent the introduction, transmission or spread of communicable disease.

Public Health Outcome

ORA accomplishes a majority of its regulatory and public health responsibilities by conducting inspections both domestically and abroad, by performing entry review on imported products, by investigating and building compliance cases, and by monitoring recalls.

In FY 2012, FDA has again exceeded the human tissue performance goal of 533 inspections, having accomplished 594 inspections. These inspections focus on the safe manufacture of HCT/Ps in accordance with the applicable regulations. HCT/Ps recovered from unknown or high risk donors could present a significant risk to human health as transmissible diseases may be present. These inspections assess manufacturers of HCT/Ps including bone, skin, corneas, ligaments, tendons, and heart valves, among others.

In addition to regulatory efforts such as inspections to monitor the manufacturing of HCT/Ps, carrying out this program entails pursuing corrective actions as well. Some representative cases include:

- In October 2011, a superseding indictment was handed down involving an individual who was conducting a clinical trial without FDA approval. This person obtained human placentas from at least one Las Vegas area hospital and surgically implanted tissue from the placenta(s) into at least 16 patients suffering from multiple sclerosis and other serious conditions. The defendants also made false representations to FDA regulatory investigators regarding their involvement in the scheme, conducted no meaningful follow-up with the patients who underwent the implant procedures, and concealed from patients and prospective patients the adverse effects suffered by previous patients. In November 2012, after a nearly four week trial, two defendants from Nevada were each convicted of all charges.

- In December of 2011, three men were charged with multiple mail fraud charges and the Introduction of a New Drug into Interstate Commerce as a result of their participation in a scheme to manufacture, distribute and sell to the public stem cells, and stem cell procedures that were not approved by the FDA. According to the indictment, the defendants in this case manufactured, distributed and used stems cells produced from umbilical cord blood to perform procedures not approved by the FDA to treat persons suffering from cancer, amyotrophic lateral sclerosis (ALS), multiple sclerosis (MS) and other autoimmune diseases. These types of efforts are given high priority as they serve to protect the most vulnerable of our population from products and treatments that are neither safe nor effective.
- In September 2012, two defendants from Texas were convicted in unrelated cases as a result of their participation in a scheme to manufacture, distribute and sell to the public stem cells, and stem cell procedures that were not approved by the FDA. These stem cell "therapies" were used to treat those suffering from cancer, ALS, MS and other autoimmune diseases. The defendants falsely represented to patients that this treatment protocol had been reviewed by all levels of the FDA and was an effective treatment for cure of the disease.

FDA's oversight helps to ensure that those in the public relying upon implanted human tissue are not exposed to potentially deadly diseases. Millions of patients receive these products each year and these inspections are conducted to ensure HCT/Ps are not contaminated, do not become contaminated during manufacturing, and do not contain communicable disease agents.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
233201: Complete review and action on standard original PDUFA NDA/BLA submissions within 10 months of receipt. *(Output)*	FY 2011: 100% Target: 90% (Target Exceeded)	90%	NA *	NA
233202: Complete review and action on priority original PDUFA NDA/BLA submissions within 6 months of receipt. *(Output)*	FY 2011: NA (No Applications Received)	90%	NA *	NA
233207: Review and act on standard NME NDA and original BLA submissions within 10 months of the 60 day filing date. *(Output)*	NA New Goal *	NA	90%	NA
233208: Review and act on priority NME NDA and original BLA submissions within 6 months of the 60 day filing date.	NA New Goal *	NA	90%	NA

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
(Output)				
233209: Review and act on standard non-NME original NDA submissions within 10 months of receipt. *(Output)*	NA New Goal *	NA	90%	NA
233210: Review and act on priority non-NME original NDA submissions within 6 months of receipt. *(Output)*	NA New Goal *	NA	90%	NA
233203: Complete review and action on standard PDUFA efficacy supplements within 10 months of receipt. *(Output)*	FY 2011: 100% Target: 90% (Target Exceeded)	90%	90%	Maintain
234203: Number of human foreign and domestic tissue establishment inspections. *(Output)*	FY 2012: 591 Target: 533 (Target Exceeded)	533	570	+37

Blood and Blood Products Premarket Review and Postmarket Safety – Center Activities

Base Amount: $94,918,070 (BA: $63,533,070/UF: $31,385,000)

Public Health Focus

The Blood and Blood Products Premarket Review and Postmarket Safety subprogram ensures the safety of blood and blood products by regulating blood establishments and approving devices used in the preparation of blood. The subprogram also regulates all Human Immunodeficiency Virus (HIV) and other retroviral diagnostic assays used in the United States.

According to the most recent National Blood Collection and Utilization Survey Report (2009), over 17 million donations of Whole Blood and Red Blood Cells were collected for transfusion in 2008 from almost 11 million donors. These donations were made into about 24 million blood components that were transfused into about 4.5 million patients. Additionally, about 20 million donations of Source Plasma were collected for further manufacture into life-saving plasma derivatives. CBER reviews and approves a wide range of life saving plasma-derived and recombinant protein products such as clotting factors, albumin, and immune globulins. These biological products impact the health of several million recipients who use these products acutely and chronically for a variety of hematologic, immunodeficiency, cancer and neurologic diseases. For example, in 2012, CBER approved immune globulin for multifocal motor neuropathy. This disease is a progressive disorder causing weakness and muscle wasting. Immune globulin is the only approved biologic product that improves muscle strength and disability in these patients.

Public Health Outcome

For all blood-related biologics, CBER establishes product standards. For many of these products, CBER develops potency standards through international collaborations. CBER promulgates regulations and issues rules and guidance documents to blood establishments on donor screening and blood safety, many of which are discussed at public Advisory Committee meetings. For example, in October 2012, CBER issued the "Final Guidance for Industry: Use of Nucleic Acid Tests on Pooled and Individual Samples from Donors of Whole Blood and Blood Components, Including Source Plasma, to Reduce the Risk of Transmission of Hepatitis B Virus ". This guidance finalized recommendations to blood establishments to test blood donations for the Hepatitis B Virus more sensitive than serologic tests to help ensure the safety of blood donations and blood products by reducing the risk of Hepatitis B Virus (HBV).
In June 2012 CBER issued a "Draft Guidance for Industry Recommendations for Donor Questioning, Deferral, Reentry and Product Management to Reduce the Risk of Transfusion-Transmitted Malaria". In the absence of any donor screening assay for Malaria, this guidance provides important policy for donor deferral to reduce the transfusion- transmitted Malaria and improving the safety of the nation's blood supply.
In September 2012 FDA issued a final guidance entitled, "Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion." This document will provide recommendations that streamline the licensing procedure for leukocyte reduced blood components and assist blood establishments in making these products more widely available for transfusion.
The FDA also held a workshop in October 2012 on Statistical Process Controls for Blood Establishments to promote understanding of how blood establishments should implement the guidance. Statistical process control is the application of statistical methods to the monitoring, or quality control, of a manufacturing process. The implementation of acceptable statistical process controls ensures that a process performs predictably to manufacture a product that meets specific standards. FDA monitors manufacturing procedures, validation summaries, and quality control data prior to licensure and during periodic inspection of facilities.

CBER ensures the safety of the blood supply by requiring blood establishments to use a system of overlapping safeguards. These safeguards include donor deferral for risks from blood borne agents, testing of blood, and checking deferral registries; quarantine of blood until checks are completed; and a requirement for establishments to investigate and report biological product deviations.

Continuous vigilance is necessary to preserve the current high level of blood safety. Since HIV and/or other viral variants may emerge at any time, they potentially could escape detection by current screening tests. CBER maintains an active program to acquire such variants and ensures that licensed donor screening tests can detect these viral variants. CBER scientists are developing reference panels to facilitate development of donor screening tests for babesiosis and dengue virus infections. CBER also regulates blood grouping tests used to type donor and patient blood to

prevent hemolytic reactions. In September 2012, CBER approved a bundled BLA submission for seven Reagent Red Blood Cell in vitro diagnostic products from Alba Bioscience Limited. These reagents are important in the confirmation of the red blood cell group and in the detection and identification of unexpected antibodies in blood samples to help ensure that compatible donor units are transfused to recipients.

CBER approved the Avioq Human T-Lymphotropic Virus (HTLV)-I/II Microelisa System, with intended use for screening living individual human donors, including volunteer donors of whole blood and blood components, for the presence of HTLV-I and HTLV-II antibodies in March 2012. HTLV-I is associated with several diseases, including a form of leukemia (adult T-cell leukemia) and a neurologic disease called HTLV-I Associated Myelopathy or Tropical Spastic Paraparesis, which is a disease of the central nervous system resulting in weakness in the legs, problems with sensation, and incontinence, among other symptoms. The HTLV blood test is the only test now available that can be used to both screen the blood supply for antibodies to HTLV Types I and II, and be used to help diagnose infection with these viruses.

CBER approved the PROCLEIX ULTRIO PLUS Assay, a qualitative multiplex donor screening test to simultaneously detect Human Immunodeficiency Virus Type 1 (HIV-1) RNA, Hepatitis C Virus (HCV) RNA, and HBV DNA in human plasma and serum specimens from donors of Whole Blood, blood components, and Source Plasma, and from other living donors. Licensure as a donor screening test for HBV DNA provides a practical and convenient assay in nucleic acid detection technology for HBV that meets a rigorous sensitivity standard and will enhance the safety of transfusion and transplantation products

CDC estimates that 1.2 million people in the United States are living with HIV infection, and that one in five is not aware that they are infected. There are about 50,000 new HIV infections every year, many of which are transmitted from people who are unaware of their HIV status. In July 2012, CBER approved the OraQuick® In-Home HIV Test, the first over-the-counter, home-use rapid HIV test kit to detect the presence of antibodies to HIV-1 and human immunodeficiency virus type 2. The test is self-administered with an oral swab and provides results within 20 to 40 minutes, allowing people to learn of their HIV status and seek medical treatment earlier if appropriate.

To enhance surveillance, CBER is developing the Blood Safety Continuous Active-Surveillance Network (Blood SCAN), to create an active pharmacovigilance system for blood and blood products. In 2012, CBER awarded a contract to support defining the clinical criteria and necessary data elements for selecting data sources to create the Blood SCAN distributed database and to evaluate current literature and assess the potential to identify blood and blood product exposure and outcomes with the current mini-Sentinel Common Data Model.

CBER also evaluates the safety of blood and blood products in Medicare beneficiaries in collaboration with the Centers for Medicare and Medicaid Services (CMS). These

efforts are being coordinated with other HHS stakeholders as part of a national biovigilance system. Data from these programs will be used to further evaluate and improve transfusion safety by early detection of new threats.

Blood and Blood Products Premarket Review and Postmarket Safety – Field Activities

Base Amount: $27,452,000 (BA: $25,374,000 / UF: $2,078,000)

Public Health Focus

ORA supports the Biologics Program in ensuring the safety, purity, potency and effectiveness blood and blood products, for the prevention, diagnosis, and treatment of human diseases, conditions, or injuries and helps to defend the public against the threats of emerging infectious diseases and bioterrorism.

Public Health Outcome

ORA accomplishes a majority of its regulatory and public health responsibilities by conducting inspections both domestically and abroad, by performing entry review on imported products, by investigating and building compliance cases, and by monitoring recalls.

In FY 2012, ORA conducted 1,061 blood bank inspections exceeding its goal of inspecting 1,000 of the highest risk registered blood bank and biological product manufacturers. While some of the inspections uncovered deviations from applicable cGMP regulations for blood and blood products which resulted in the issuance of warning letters but no product recalls, the majority of the inspections found the facilities to be operating in accordance with FDA requirements, thus ensuring the safety of their products.

In May of 2012, a defendant living in Palm Beach, Florida, was convicted of distributing adulterated home test kits. The defendant owned and operated a company through which he sold to the general public various test kits for sexually transmitted diseases, including kits to test for HIV and hepatitis. The test kits lacked pre-market FDA approval and had no FDA-granted investigational device exemption. Additionally, the defendant's website contained false statements about the company and the test kits, including statements that the test kits were FDA registered devices. The impact of this case, and similar investigations conducted by the Office of Criminal Investigations, is to reduce the number of unapproved and substandard testing kits, and thereby protect the public from the risks of false test results, particularly false negative readings that could cause a person not to seek appropriate medical treatment.

FDA's inspections help to ensure the nation's blood supply is safe and free of infectious disease, which is transmissible to patients receiving blood products. In addition, blood, blood products, and other biological sources must be safe as they are used to produce

important biological drug products for treating many diseases and are on the forefront of new treatment therapies available to patients where no therapies may have existed previously.

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In May of 2012, a defendant living in Palm Beach, Florida, was convicted of distributing adulterated home test kits. The defendant owned and operated a company called At First Diagnostics through which he sold to the general public various test kits for sexually transmitted diseases, including kits to test for HIV and hepatitis. The test kits, known as FirstVue HIV Test Kit and FirstVue HCV Test Kit, lacked pre-market FDA approval and had no FDA-granted investigational device exemption. Additionally, the defendant's website contained false statements about the company and the test kits, including statements that At First Diagnostics developed and manufactured the test kits; that the test kits were FDA registered devices; and that At First Diagnostics had offices in Ireland, Spain, California, New Jersey and New York. The impact of this case, and similar investigations conducted by the Office of Criminal Investigations, is to reduce the number of unapproved and substandard testing kits, and thereby protect the public from the risks of false test results, particularly false negative readings that could cause a person not to seek appropriate medical treatment.

FDA's inspections help to ensure the nation's blood supply is safe and free of infectious disease, which is transmissible to patients receiving blood products. In addition, blood, blood products, and other biological sources must be safe as they are used to produce important biological drug products for treating many diseases and are on the forefront of new treatment therapies available to patients where no therapies may have existed previously.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
233205: Complete review and action on complete blood bank and source plasma BLA submissions within 12 months after submission date. *(Output)*	FY 2011: 100% Target: 90% (Target Exceeded)	90%	90%	Maintain
233206: Complete review and action on complete blood bank and source plasma BLA supplements within 12 months after submission date. *(Output)*	FY 2011: 99% Target: 90% (Target Exceeded)	90%	90%	Maintain
234202: Number of registered domestic blood bank and biologics manufacturing inspections. *(Output)*	FY 2012: 1,073 Target: 1,000 (Target Exceeded)	1,000	1,000	Maintain

Information Technology Investments – Biologics Program Activities (Base Amount displayed as a non-add item: $45,980,248)

FDA is continuing to modernize and enhance its information technology (IT) infrastructure to provide a more robust and responsive foundation to support all FDA programs. These efforts are providing a foundation on which to bolster FDA's broad and very dynamic scientific and regulatory responsibilities. Agency-wide costs associated with the operation and maintenance of this infrastructure includes two data centers, telecommunication networks, IT security and help desk functions. While these functions are supported at the agency level, each center and office has program specific IT systems with objectives that range from improving the premarket review process for all regulated products to post-market surveillance, including adverse event detection, and future scientific computing capabilities. This common infrastructure facilitates consolidation and meets Executive Order 13514 related to energy efficiency, HHS and OMB mandates with respect to green computing, cloud computing, and virtualization.

IT infrastructure, FDA-wide enterprise investments and existing center-specific IT systems are planned to be augmented by further automating the Managed Review Process. To support increased automation, CBER plans to further implement the Health Level Seven, Regulated Product Submissions (RPS) message format. This expansion will support the PDUFA IT two-way communication goal and enable more efficient communications between FDA and the regulated community. CBER will enhance Electronic Document Room and other supporting IT systems, to include support for automatic receipt and processing of RPS messages. CBER will enhance the capabilities of the safety reporting systems and consolidate safety reporting

databases. The consolidation will enable a greater level of reporting and signal detection across product areas. CBER will expand the Electronic Managed Review Process to include additional manual processes which will streamline those activities and enable improvements to review quality. These enhancements will increase CBER reviewer access to large datasets, enhancing their ability to analyze and monitor the safety of biological products such as vaccines, which is especially crucial in the case of emerging infectious disease or possible pandemics.

Funding History Table with FTE Totals

The following table displays funding and FTE staffing levels from FY 2010 through FY 2014.

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
FY 2010 Actual	$291,430,000	$205,542,000	$85,888,000	1,250
FY 2011 Actual	$302,020,000	$211,790,000	$90,230,000	1,296
FY 2012 Actual	$308,620,000	$212,298,000	$96,322,000	1,319
FY 2013 CR	$334,469,000	$213,523,000	$120,946,000	1,342
FY 2014 PB	$337,946,000	$210,759,000	$127,187,000	1,356

Summary of the Budget Request

The FY 2014 budget request for the Biologics Program is $337,946,000. This amount is an increase of $8,810,000 above the FY 2012 Enacted level. The **Center for Biologics Evaluation and Research** amount in this request is $292,417,000, which supports 1,115 FTE. The ORA Field Biologics amount is $45,529,000 supporting 241 FTE.

The base funding for the Biologics Program is $329,136,000, which includes $283,904,000 for the Biologics Center activities and $45,232,000 for the Biologics Field activities.

Base funding allows the Biologics Program to meet its mission of ensuring that blood, blood products, vaccines, tissues and cell and gene therapies are available to the American public. It will also advance public health through innovative regulation that promotes the safety, effectiveness, and timely delivery of biological products to patients. CBER and ORA will focus on high priority areas facilitating:

- The safety of the nation's blood supply and the products derived from blood
- The production and approval of safe and effective adult and childhood vaccines
- The oversight of human tissues for transplantation
- The development of safe and effective cell and gene therapies
- An adequate and safe supply of allergenic materials and anti-toxins.

The initiatives proposed under the FY 2014 budget request support HHS, FDA and Presidential public health priorities and mission-critical program activities to advance FDA's Medical Countermeasures Initiative.

Budget Request Details

Pay Increase (Total Program: +$932,000)

The request for $210,759,000 in total budget authority for the Biologics Program reflects a pay increase for +$932,000. The Center's portion of this increase is +$755,000 and the Field's portion is +$177,000.

Adjustment to Base (Total Program: -$2,649,000 and –13 FTE)

The budget request for $210,759,000 in total budget authority for the Biologics Program also reflects a reduction to the base of $2,649,000 for FY 2014. The Center's portion of this reduction is -$2,143,000 and –11 FTE; the Field's portion of this reduction is -$506,000 and -2 FTE.

Vaccines Premarket Review and Postmarket Safety

Center Activities –
FY 2012 Enacted Base: $135,148,740 (BA: $75,552,840/ UF: $59,595,900)
FY 2014 Total Increase above Base: (+$5,570,900 / +6 FTE)
FY 2014 Increase above Base for Current Law User Fees (PDUFA): (+$5,300,000/+5 FTE)
FY 2014 Increase above Base for User Fees (BsUFA): (+$270,900 / +1 FTE)

Field Activities –
FY 2012 Enacted Base: $5,842,000 (BA: $4,383,000 / UF: $1,459,000)
FY 2014 Total increase above Base: (+$193,000 / 0 FTE)
FY 2014 Increase above Base for Current Law User Fees (PDUFA): (+$130,000 / 0 FTE)
FY 2014 Increase above Base for Proposed User Fees (Medical Products Reinspection): (+$63,000 / 0 FTE)

Cells, Tissues and Gene Therapy Premarket Review and Postmarket Safety

Center Activities –
FY 2012 Enacted Base: $53,837,190 (BA: $32,625,090/ UF: $21,212,100)
FY 2014 Total increase above Base: (+$2,113,100/ +2 FTE)
FY 2014 Increase above Base for Current Law User Fees (PDUFA): (+$1,886,000/ +2 FTE)
FY 2014 Increase above Base for User Fees (BsUFA): (+$116,100/ 0 FTE)
FY 2014 Increase above Base for User Fees (GDUFA): (+$111,000/ 0 FTE)

Field Activities –
FY 2012 Enacted Base: $11,938,000(BA: $10,756,000 / UF: $1,182,000)
FY 2014 Total Increase above Base: (+$246,000 / +2 FTE)
FY 2014 Increase above Base for Current Law User Fees (PDUFA): (+$105,000 / 0 FTE)
FY 2014 Increase above Base for Proposed User Fees (Medical Products Reinspection): (+$141,000 / +1 FTE)

Blood and Blood Products Premarket Review and Postmarket Safety

Center Activities –
FY 2012 Enacted Base: $94,918,070 (BA: $63,533,070/ UF: $31,385,000)
FY 2014 Total increase above Base: (+$2,217,000/+9 FTE)
FY 2014 Increase above Base for Current Law User Fees (PDUFA): (+$1,797,000/+1 FTE)
FY 2014 Decrease below Base for Current Law User Fees (MDUFA): (-$882,000/ +3 FTE)
FY 2014 Increase above Base for User Fees (BsUFA): (+$387,000/ +2 FTE)
FY 2014 Increase above Base for User Fees (GDUFA): (+$663,000/ +3 FTE)

FY 2014 Initiative Increases above Base:

Medical Countermeasures:
+$252,000 / (1 FTE non-add)

CBER will sustain its MCM regulatory science program, relying heavily on partnerships with industry, academia and U.S. government partners that enable FDA to harness cutting-edge science and apply innovative approaches to the regulatory process to improve MCM development timelines and success rates. In particular, FDA will focus investments in regulatory science on:

- Developing and qualifying tools to assess efficacy, such as animal and biomimetic models
- Developing methods to assess product quality and assays to support the release of MCMs

Field Activities –
FY 2012 Enacted Base: $27,452,000 (BA: $25,374,000 / UF: $2,078,000)
FY 2014 Total Decrease below Base: (-$187,000 / +2 FTE)
FY 2014 Increase above Base for Current Law User Fees (PDUFA): (+$139,000 / 0 FTE)
FY 2014 Decrease below Base for Current Law User Fees (MDUFA): (-$320,000 / +1 FTE)
FY 2014 Increase above Base for Proposed User Fees (Medical Products Reinspection): (+$368,000 / +2 FTE)

BIOLOGICS PROGRAM ACTIVITY DATA

Workload and Outputs	FY 2012 Actual	FY 2013[1] Estimate	FY 2014 Request
NDA/BLA Submissions			
Applications received Standard: Priority:	 36 2	 39 2	 39 2
Applications completed [1/] Standard: Priority:	 15 0	 16 1	 16 1
Applications approved [2/] Standard: Priority:	 11 0	 12 1	 12 1
Applications pending [3/] Standard: Priority:	 51 5	 55 6	 55 6
Efficacy Supplements			
Applications received Standard: Priority:	 8 1	 9 2	 9 2
Applications completed [1/] Standard: Priority:	 5 0	 6 1	 6 1
Application approved [2/] Standard: Priority:	 23 1	 25 2	 25 2
Applications pending [3/] Standard: Priority:	 12 0	 13 1	 13 1
Original Manufacturing Supplement			
Applications received	1,133	1,227	1,227
Applications completed [1/]	255	276	276
Applications approved [2/]	1,183	1,282	1,282
Applications pending [3/]	713	772	772

Workload and Outputs	FY 2012 Actual	FY 2013[1] Estimate	FY 2014 Request
Device Premarket Applications - PMAs			
Applications received Supplements received	3 37	4 40	4 40
Applications completed [1/] Supplements completed [1/]	0 20	1 22	1 22
Applications approved [2/] Supplements approved [2/]	1 17	2 19	2 19
Applications pending [3/] Supplements pending [3/]	3 7	4 8	4 8
Device 510(k)s			
Applications received	54	59	59
Applications completed [1/]	69	75	75
Applications approved [2/]	41	45	45
Applications pending [3/]	17	19	19
Investigational Applications			
Commercial IND/IDE Receipts [4/]	145	157	157
IND/IDE Amendment Receipts [4/]	10,149	10,995	10,995
Active INDs/IDEs [4/]	2,614	2,832	2,832
Other Activities			
Patient Safety			
Adverse Event Reports Received [5/]	35,083	38,000	40,000
Biological Product Deviation Reports Received	55,843	56,000	56,000
Sponsor Assistance/Outreach			
Meetings	390	423	423
Final Guidance Documents [6/]	21	20	20
Admin/Management Support			
Advisory Committee meetings held	14	20	19
FOI requests processed	350	350	350

[1] Spending authority has been adjusted pursuant to PL 112-175, Section 101(c) for the applicable user fee programs.
1/ Complete action letter was sent to sponsor. Includes withdrawn, denied, NSE, and exempts.
2/ Includes all applications approved during the fiscal year, regardless of year of receipt.
3/ Includes applications for which complete action has not been achieved at the end of the fiscal year. It does not mean the application is overdue.
4/ Includes IND, IDE, Master File and license master file receipts.
5/ Includes MedWatch, Foreign reports and VAERS reports. Does not include Fatality Reports or Medical Device Reports for CBER-regulated medical devices.
6/ Includes all FDA final guidances issued by CBER and other FDA centers that pertain to biological products.

Combined Field Activities – ORA
Program Activity Data

Field Biologics Program Activity Data (PAD)

Field Biologics Program Workload and Outputs	FY 2012 Actuals	FY 2013[1] Estimate		FY 2014 Request
FDA WORK				
DOMESTIC INSPECTIONS				
UNIQUE COUNT OF FDA DOMESTIC BIOLOGICS ESTABLISHMENT INSPECTIONS	***1,972***	***2,047***		***2,047***
Bioresearch Monitoring Program Inspections	98	100		100
Blood Bank Inspections	1,061	1,060		1,060
Source Plasma Inspections	190	194		194
Pre-License, Pre-Market Inspections	7	7		7
GMP Inspections	26	28		28
GMP (Device) Inspections	7	7		7
Human Tissue Inspections	593	661	1	661
FOREIGN INSPECTIONS				
UNIQUE COUNT OF FDA FOREIGN BIOLOGICS ESTABLISHMENT INSPECTIONS	***50***	***47***		***47***
Bioresearch Monitoring Program Inspections	11	11		11
Foreign Human Tissue Inspections	1	0		0
Blood Bank Inspections	8	8		8
Pre-License Inspections	2	2		2
GMP Inspections	22	20		20
TOTAL UNIQUE COUNT OF FDA BIOLOGIC ESTABLISHMENT INSPECTIONS	***2,022***	***2,094***		***2,094***
IMPORTS				
Import Field Exams/Tests	45	45		45
Import Line Decisions	65,469	79,771		97,198
Percent of Import Lines Physically Examined	0.07%	0.06%		0.05%
GRAND TOTAL BIOLOGICS ESTABLISHMENT INSPECTIONS	***2,022***	***2,094***		***2,094***

[1]Spending authority has been adjusted pursuant to PL 112-175, Section 101(c) for the applicable user fee programs.

[1] For ORA investigators hired with FY 2011 BA enacted increases, the full performance year is FY 2013 for domestic human tissue inspections. During the full performance year (FY 2013), the FY 2011 BA enacted funding increases for inspections will allow ORA to conduct an additional 68 domestic human tissue inspections.

Animal Drugs and Feeds Program

The following table displays the funding and full time equivalent (FTE) staffing levels for FY 2012 through FY 2014.

FDA Program Resource Table

Animal Drugs and Feeds
(Dollars in thousands)

	FY 2012 Enacted	FY 2012 Actual	FY 2013[2] CR	FY 2014 PB	+/- FY 2012
Program Level	**$165,256**	**$156,909**	**$166,268**	**$190,753**	**$25,497**
Center	$108,387	$103,455	$109,050	$118,426	$10,039
FTE	501	515	519	524	9
Field Activities	$56,869	$53,454	$57,218	$72,327	**$15,458**
FTE	312	281	306	340	59
Program Level FTE	**813**	**796**	**825**	**864**	68
Budget Authority	**$136,912**	**$137,964**	**$137,750**	**$141,566**	**$4,654**
Center	$83,707	$84,651	$84,219	$87,846	$4,139
Field Activities	$53,205	$53,313	$53,531	$53,720	$515
Budget Authority FTE	**702**	**713**	**714**	**712**	**(1)**
Center	413	433	430	423	(10)
Field Activities	289	280	284	289	9
User Fees	**$28,344**	**$18,945**	**$28,518**	**$49,187**	**$20,843**
Center ADUFA	**$19,261**	**$14,723**	**$19,379**	**$20,768**	**$1,507**
FTE	66	62	67	67	5
Field ADUFA	**$315**	**$141**	**$317**	**$472**	**$157**
FTE	2	1	1	1	-
Center AGDUFA	**$4,898**	**$4,081**	**$4,928**	**$6,302**	**$1,404**
FTE	20	20	20	20	**-**
Field AGDUFA	**$160**	**$0**	**$161**	**$220**	$60
FTE	1	0	1	1	1
Field Food Reinspection User Fee	**$2,550**	**$0**	**$2,566**	**$2,666**	**$116**
FTE	18	0	18	18	18
Food and Feed Recall User Fee	**$1,160**	**$0**	**$1,167**	**$1,213**	**$53**
Center	$521	$0	$524	$545	$24
FTE	2	0	2	2	2
Field Activities	$639	$0	$643	$668	$29
FTE	2	0	2	2	2
Field Medical Products Reinspection[1]				**$143**	**$143**
FTE				1	1
Food Facility Establishment Registration and Inspection User Fee [1]				**$2,544**	**$2,544**
Center				$1,526	$1,526
FTE				6	6
Field Activities				$1,018	$1,018
FTE				2	2
Food Import User Fee[1]				**$14,859**	**$14,859**
Center				$1,439	$1,439
FTE				6	6
Field Activities				$13,420	$13,420
FTE				26	26
User Fees FTE	**111**	**83**	**111**	**152**	**69**

[1] Proposed User fee; the amount includes associated rent activity.

[2] Spending authority has been adjusted pursuant to PL 112-175, Section 101(c) for the applicable user fee programs.

The FDA Animal Drugs and Feeds Program operates under the following legal authorities:
Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 321-399)
Public Health Service Act (1944) (42 U.S.C. 264, 271)
Animal Drug Amendments (1968) (21 U.S.C. 360b)
Generic Animal Drug and Patent Term Restoration Act (1988)*
Animal Medicinal Drug Use Clarification Act of 1994*
Animal Drug Availability Act of 1996*
FDA Export Reform and Enhancement Act of 1996*
Food and Drug Administration Modernization Act of 1997*
Public Health Security and Bioterrorism Preparedness Response Act of 2002*
Animal Drug User Fee Act of 2003 (21 U.S.C. 379j-11 - 379j-12)
Minor Use and Minor Species Animal Health Act of 2004*
Food and Drug Administration Amendments Act of 2007 (FDAAA)*
Animal Drug User Fee Amendments of 2008 (P.L. 110-316)
Animal Generic Drug User Fee Act of 2008 (P.L. 110-316)
FDA Food Safety Modernization Act (P.L. 111-353)
Protecting Patients and Affordable Care Act of 2010*
FDA Safety and Innovation Act (P.L. 112-144)

Allocation Method: Direct Federal/intramural; Contract; Competitive grant

Program Description and Accomplishments

The Animal Drugs and Feeds Program is a component of the FDA Foods and Veterinary Medicine (FVM) Program. The mission of the FVM Program is to protect and promote the health of humans and animals by ensuring the safety of the American food supply, as well as the safety of animal feed and the safety and effectiveness of animal drugs and devices. The FVM Program is comprised of the Foods and the Animal Drugs and Feeds Programs, with the Office of Food and Veterinary Medicine providing leadership and strategic direction. The Foods and the Animal Drugs and Feeds Programs are administered by the Center for Food Safety and Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM) respectfully, both in collaboration with the Office of Regulatory Affairs (ORA).

The Animal Drugs and Feeds Program began in 1968 with the amendment of the Federal Food, Drug and Cosmetic (FD&C) Act to include new authorities for regulating animal drugs, devices, and additives used in animal feed. The Program supports FDA's mission by approving safe and effective products for animals and by enforcing applicable provisions of the FD&C Act and other authorities. Safe and effective animal drugs and feed additives play an important role in protecting animal health and the safety of America's food supply.

* Authorities under this act do not appear in sequence in the U.S. Code. The authorities are codified as amended in scattered sections of 21 U.S.C.

Congress recognized the unique challenges faced by FDA in the area of food safety in the 21st century, and gave FDA a modern legislative mandate to meet these challenges by enacting the FDA Food Safety Modernization Act of 2011 (FSMA). FSMA directs FDA to build a food safety system based on the public health principle of comprehensive prevention, an enhanced focus on risk-based resource allocation, and partnership across the public and private sectors to minimize hazards from farm to table.

The FDA *Foods and Veterinary Medicine Program (FVM) Strategic Plan*[34] provides a framework for the implementation of FSMA, places high priority on the prevention of foodborne illness of unknown origins and illness that can be specifically attributed to known sources, as well as regulating the safety and effectiveness of animal drugs.

In order to achieve the goals of the *FVM Strategic Plan*, the program ensures that animal drugs and feeds used in the care of food producing animals do not result in unsafe residues in food products that are harvested or produced (e.g. milk) from these animals. The program also protects the health of companion animals and addresses zoonotic diseases – animal diseases that can be transmitted to humans. Further, the program focuses on providing timely premarket review of new animal drugs, ensuring that approved drugs are being used appropriately, providing scientific research solutions that ensure safety of the animal derived food and health products, putting measures in place to minimize the illegal sale of unapproved drugs and preventing marketing of unsafe products. These efforts contribute to a food supply that is safe for both humans and animals, and protects billions of poultry, cattle, swine, horses and minor animal species, as well as more than 150 million companion animals in the United States.

A combination of appropriations and user fee programs fund the regulatory process to assure product safety and effectiveness. User fees are authorized under the Animal Drug User Fee Act (ADUFA), the Animal Generic Drug User Fee Act (AGDUFA), the FDA Export Reform and Enhancement Act (Export Certification program) and FSMA. The ADUFA and AGDUFA user fee programs supplement the appropriated portion of the new animal drug review program to continue improving the quality and timeliness of the new animal drug and animal generic drug review processes. The Export Certification user fee program promotes the export of products made in the U.S. and facilitates international trade. The FSMA Food and Feed Safety Recall user fee program reimburses FDA for the cost of conducting a mandatory recall of an article of food or feed that is adulterated or misbranded.

[34] The strategic plan can be found on the FDA web site at:
http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofFoods/UCM273732.pdf

To support the Animal Drugs and Feeds Program, ORA Field offices support CVM activities by:

- Assessing industry compliance with applicable laws and regulations to protect human and animal health
- Conducting premarket and postmarket risk-based inspections of domestic and foreign establishments to determine the safety of manufactured products
- Performing laboratory analysis to support inspections and conducting surveillance activities of animal drugs and feeds
- Monitoring and sampling import products to ensure the safety of animal drugs and food defense related security of the feed supply
- Overseeing and evaluating the effectiveness of recalls of violative products
- Conducting surveillance and enforcement related activities
- Funding and overseeing contracts with state food regulatory agencies to conduct inspections, collect and conduct sample analysis on regulated food products
- Collaborating with state, local, tribal, and territory counterparts to further FDA's feed and food safety missions
- Funding and overseeing grants and cooperative agreements to support the capacity building of state, local, tribal and territory regulatory counterparts.

The Animal Drugs and Feeds Program executes its regulatory responsibilities in six subprogram areas:

Foods Related

- Prioritizing Prevention
- Strengthening Surveillance
- Strengthening Enforcement
- Improving Response and Recovery

Non-Foods Related

- Animal Drug Review
- Postmarket Safety and Compliance

Prioritizing Prevention – Center Activities
Base Amount: $39,659,000 (BA: $25,164,000 / UF: $14,495,000)

Public Health Focus and FDA Food Safety Strategy

Prevention is the cornerstone of an effective and proactive food and feed safety strategy. CVM is able to protect human and animal health by establishing preventive control safety standards and practices, and conducting research and outreach activities to protect feed supplies from contamination, consistent with the *FVM Strategic Plan*.

CVM supports the *FVM Strategic Plan* goals of establishing science-based preventive control standards across the farm-to-table continuum, achieving high rates of compliance with preventive controls standards domestically and internationally, strengthening scientific leadership, capacity, and partnership to support human and animal health decision making, and advancing animal drug safety and effectiveness. This includes the adoption of science-based regulations that protect the food and feed supply from contamination, identification of the most significant food-borne contaminants, and evaluation of the effectiveness of existing controls for those contaminants.

Public Health Outcome

CVM reviews and approves animal drug applications, establishes standards for feed contaminants, conducts scientific research to support development of new standards and the premarket review process, and reviews and approves safe food additives. In addition, CVM works with all stakeholders to promote responsibility through the identification, development, and implementation of new regulations to further support the production of safe feed for all animals.

CVM reviews and approves new animal drug applications – pioneer and generic – for the effect on the targeted animal users and human users who may consume food produced from the animal. CVM works to minimize delays in bringing animal drugs to market, including products developed using new technologies, such as biotechnology (genetically engineered animals and cloning). Bringing animal drugs to the market quickly helps to ensure the public has access to safe and effective drugs on a timely basis. This access protects human and animal health by reducing the use of unapproved animal drugs, including illegally compounded animal drugs and improperly labeled drugs, used to treat animal diseases. As of August 2012, CVM completed review of and action on 99.8 percent of New Animal Drug Applications and other ADUFA sentinel submissions in timeframes specified by the controlling user fee acts for those applications reviewed during FY 2012, thus exceeding the performance goal by 9.8 percent on more than 4,594 total submissions. CVM also completed review of and action on 100 percent of Abbreviated New Animal Drugs Applications and other AGDUFA sentinel submissions in timeframes specified by the controlling user fee acts for those applications reviewed during FY 2012. The review and completion of these applications within specified timeframes also exceeded the performance goal by 10 percent on 858 total submissions.

In addition, CVM reviews conditional drug approvals and index and designation requests to increase the number of safe and effective new animal drug products for minor animal species and uncommon diseases in major animal species. Further, CVM administers a grant program to support the development of new animal drugs intended for minor species or minor uses in major species. As of November 2012, CVM had granted 112 drug designations, mostly related to aquaculture, and 4 legally marketed unapproved new animal drugs for minor species in the index.

Pursuant to FSMA, FDA is developing a broader regulatory approach to address animal food safety issues associated with the production, processing, transporting and preparing of animal food, including pet food, animal feed, raw materials and ingredients. The regulations are intended to prevent animal food containing hazards, which may cause illness or injury to animals or humans, from entering the food supply. These regulations will require written food safety plans for facilities that are required to register with FDA under the FD&C Act.
In the area of regulatory research, CVM scientists are working on essential innovation methods research aimed at addressing new veterinary drug safety and efficacy challenges presented by cutting-edge medical technologies, such as nanotechnologies and proteomics. In FY 2012, CVM completed the first nanotechnology study entitled "Effect of Nanogold Particles on Genomic Assays." The outcome of this research study will provide CVM with the ability to develop study protocol recommendations, proposed label language for nanotech drug delivery, and provide essential food safety data on biological distribution of nanotech drugs though edible food tissues. In addition, genomic and proteomic methods are being developed to identify specific biomarkers used to verify specific label claims and identify possible adverse reactions. These efforts will result in more safe veterinary products and decrease the extra-label use of many drugs.

In an effort to improve public awareness of animal and human health issues, CVM continues to enhance Animal Health Literacy. Animal Health Literacy promotes the use of social media, such as an Animal Health Twitter account, to connect with consumers, veterinarians and industry to share important animal health and safety tips, human and animal health updates and product recalls. Information is also disseminated to consumers through a variety of methods such as articles, brochures, newsletters and posters. In March 2012, CVM released a video for consumers about pet food entitled "FDA and Pet Food" that describes the requirements FDA places on pet food manufacturers before they can sell their products in the United States.

Prioritizing Prevention – Field Activities
Base Amount: $12,288,000 (All BA)

Public Health Focus and FDA Food Safety Strategy

ORA focuses on prevention through outreach coordination and technical assistance. In addition, internal and external training is a top field priority to gain expertise and encourage collaboration with both internal and external stakeholders.

ORA contributes to the overall FSMA strategy by focusing on preventing food safety hazards rather than reacting after they have occurred. ORA continues to work towards implementing the FSMA provisions, this is being accomplished through the development, implementation, and enforcement of regulations, standards and guidance documents. All of these activities are reflected within the *FVM Strategic Plan* goal of establishing science and risk based preventive control standards across the farm-to-

table continuum. These activities include the adoption of science and risked based regulations that protect the food and feed supply from contamination, including the identification of the most significant foodborne contaminants and an evaluation of the effectiveness of existing controls for those contaminants.

Public Health Outcome

In FY 2012, import field investigators performed more than 7,000 field and label examinations on entry lines of animal drugs and feeds. These activities were performed to identify violations, such as verifying the product matches the information transmitted electronically and the product labeling meets applicable compliance requirements. While performing an examination of a foreign manufactured dietary supplement for pet use offered for import into the U.S. in FY 2012, ORA investigators determined that a product lacked an approved new animal drug application. ORA refused the entry and took regulatory action to ensure the shipment was not distributed in the United States. These activities continue to assure that unapproved products are not distributed into U.S. commerce and are re-exported or destroyed as required under the FD&C Act.

During FY 2012, ORA issued seven notices identifying modifications to Import Alerts encompassing numerous animal drugs and feed manufacturers and products. These actions resulted from ORA import surveillance collections and testing of regulated drug products when they were offered for import into the United States, and “for cause” sampling of imported products based on findings of violations during inspections of foreign manufacturers. These notices provide increased coverage at the border to assure that non-compliant products are not made available to the U.S. consumer.

ORA leverages outreach opportunities to raise awareness and understanding of current policies and guidance as well as provide insight and information related to pending and newly issued requirements. In FY 2012, ORA participated in more than 50 outreach events including the National Customs Brokers and the Forwarders Association of America, Inc. 38th annual conference. ORA provided updates related to import initiatives; most notably, updates related to the status of FDA’s efforts to implement the import related sections of FSMA.

ORA outreach efforts also included participation in a variety of public outreach activities attended by regulated industry, other government agencies and foreign regulatory entities. In FY 2012, ORA awarded 35 contracts to states under the Feed Safety Bovine Spongiform Encephalopathy (BSE) contract program. These contracts provided assistance to FDA in establishing an expanded level of inspection coverage as well as surveillance and education, greatly enhancing regulatory oversight.

Performance Measures

The Animal Drugs and Feeds Program is supported by the ADUFA and AGDUFA user fee programs. Under ADUFA and AGDUFA, FDA agreed to pursue a comprehensive set of animal drug review performance goals.

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
243201: Complete review and action on original New Animal Drug Applications (NADAs) and reactivations of such applications received during the fiscal year. *(Output)*	FY 2012: 100% w/in 180 days Target: 90% w/in 180 days (Target Exceeded)	90% w/in 180 days	90% w/in 180 days	Maintain
243202: Complete review and action on Non-administrative original Abbreviated New Animal Drug Applications (ANADAs) and reactivations of such applications received during the fiscal year. *(Output)*	FY 2011: 100% w/in 500 days Target: 90%w/in 500 days (Target Exceeded)	90% w/in 380 days	90% w/in 270 days	-110 days

Strengthening Surveillance and Enforcement – A. Strengthening Surveillance – Center Activities

Base Amount: $13,311,000 (All BA)

Public Health Focus and FDA Food Safety Strategy

CVM protects human and animal health by monitoring marketed animal drugs, devices, and additives used in animal feed to assure their safety and effectiveness. New animal drug products are carefully tested before they are marketed. However, wider use of the drug products may result in the discovery of problems not evident during premarket research and review. The assessment of new animal drug safety is a continuing process that takes place throughout the development and marketing of a drug. As animal drugs are used to treat and prevent illnesses in food producing animals, post-market surveillance is critical to ensure the safety of our food supply. If public health warrants, CVM may recommend withdrawal of an approved drug if it is found to be unsafe or ineffective.

CVM supports the *FVM Strategic Plan* goals of strengthening scientific leadership, capacity, and partnership to support human and animal health decision making, providing accurate and useful information so consumers can choose a healthier diet and reduce the risk of chronic disease and obesity, and advancing animal drug safety and effectiveness.

Public Health Outcome

CVM reviews and analyzes information from adverse experience reports to protect consumers and animals and ensure the safety of products throughout their life cycle. CVM, in cooperation with FDA Field Offices, monitors the safety and effectiveness of approved animal drugs, devices and additives used in animal feed to protect human and animal health after they enter the market. In addition, CVM works with the U.S. Department of Agriculture (USDA) and state agencies to monitor drug residues in meat, dairy and poultry products and conducts educational activities. CVM also conducts surveillance to protect animal feed from contamination by mycotoxins, pesticides, heavy metals, industrial chemicals and other toxic materials.

CVM is strengthening the National Antimicrobial Resistance Monitoring System (NARMS) by improving sampling strategies across the animal and retail meat components of NARMS. CVM, in partnership with the USDA, completed four on-farm pilot studies and initiated a fifth study to estimate the prevalence of target food-borne bacteria in the gut of dairy and beef cattle, chickens, turkeys and swine. The goal was to measure antibiotic use and prevalence of antibiotic resistance in dairy, feedlot, and poultry species for a short term. These results will be used as a pilot to design a long-term enhancement of the animal sampling program for NARMS.

CVM is taking steps to protect human health and promote the judicious use of medically important antibiotics in food-producing animals. To help preserve the effectiveness of medically important antimicrobials for treating disease in humans, FDA proposed a voluntary initiative to phase in certain changes in how medically important antimicrobial drugs are labeled and used in food-producing animals. In April 2012, FDA issued draft text for a proposed regulation intended to improve the efficiency of FDA's Veterinary Feed Directive (VFD) program, guidance for industry 209 entitled ''The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals'', and draft guidance for industry 213 entitled ''New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions With GFI #209''. These three documents will help veterinarians, farmers and animal producers use medically important antibiotics judiciously in food-producing animals by targeting their use to only address diseases and health problems. Under this new voluntary initiative, certain antibiotics would not be used for so-called "production" purposes, such as to enhance growth or improve feed efficiency in an animal. These antibiotics would still be available to prevent, control or treat illnesses in food-producing animals under the supervision of a veterinarian.

In April 2012, CVM issued an order prohibiting certain extra-label uses of cephalosporins in cattle, swine, chickens and turkeys to preserve the effectiveness of this medically important class of drugs for treating disease in humans. The order was issued for comment on January 6, 2012, and was put into effect on April 5, 2012.

As a requirement of the Food and Drug Administration Amendments Act of 2007 (FDAAA), CVM utilizes the existing Pet Food Early Warning Surveillance System as a mechanism for detecting issues with pet food and other animal feeds. With this system, CVM can quickly and effectively identify animal food product problems and outbreaks of illness and provide notice to veterinarians and stakeholders during recalls. As a component of the system, the Partnership for Food Protection and CVM launched the Pet Event Tracking Network (PETNet) in August 2011. PETNet is a voluntary, secure, web-based information exchange, surveillance and alert system that is currently made up of more than 200 representatives from federal and state agencies to share information about emerging pet food related incidents, such as illness associated with the consumption of pet food or pet food product defects.

Strengthening Surveillance and Enforcement – A. Strengthening Surveillance – Field Activities

Base Amount: $13,657,000 (All BA)

Public Health Focus *and FDA Food Safety Strategy*

Laboratory activities include sample analysis, product testing and methods development to enable FDA to develop solutions for specific regulatory problems. ORA applies risk-based principles to the life cycle of ORA scientific operations, including sample collection, sample analysis, data reporting and data analysis.

In the case of Strengthening Surveillance, ORA achieves FSMA strategy by implementing the development of risk-based systems. This implementation includes:

- Establishing a structure to enhance risk-based decision making
- Developing metrics and goals for risk-based food and feed safety priority setting and a model for more evidence-based resource planning
- Maintaining and strengthening mission-critical scientific capabilities
- Improving centralized planning and performance metrics
- Improving information sharing both internally and externally.

Public Health Outcome

To strengthen animal food and feed defense and safety surveillance and risk analysis, ORA conducts:

- Import prior notice and entry reviews
- Import field exams

- Import sample collections
- Laboratory analyses.

In FY 2012, ORA collected milk samples as part of an on-going assignment. The assignment calls for the collection of more than 1,800 milk samples to be analyzed for the presence of drug residues. ORA laboratories developed and validated two multi-residue screening methods that analyze a total of 31 drug residues in each milk sample. The results of the assignment will provide FDA with the information it needs to determine whether dairy farms with histories of drug residue violations in meat from culled adult dairy cattle may also have unacceptable drug residues in milk. FDA will work with industry to develop an action plan to address any potential public health issues.

In FY 2012, ORA collected poultry feed as an extension of an on-going *Salmonella* assignment. ORA collected 79 samples of poultry feed and analyzed them in the FDA laboratories for *Salmonella.* If the samples contained certain *Salmonella* serotypes that could be harmful to poultry, they were deemed unacceptable for feeding chickens.

ORA utilizes a combination of techniques to perform import surveillance, including:

- Electronic information technology for risk-based entry screening
- Intensive ORA staff surveillance
- Physical exams
- Laboratory analysis.

Because the number and complexity of FDA-regulated imported products is increasing exponentially, ORA increased its efforts to strengthen surveillance and risk based analysis. For example, ORA

- Issued seven notices identifying modifications to animal drugs and feed related Import Alerts
- Conducted routine surveillance examinations, sampling, and analysis
- Conducted targeted inspection and sample collection and analysis assignments
- Established a committee in collaboration with the Association of American Feed Control Officials (AAFCO) consisting of state and FDA officials to develop Animal Feed Regulatory Program Standards (AFRPS).

In FY 2012, ORA, in collaboration with Customs and Border Protection (CBP), conducted examinations of imported food and feed shipments to identify shipments that contain smuggled human food and animal feed products. ORA and CBP have conducted more than 1,100 examinations and has taken action against several entries that contained smuggled products. Smuggled animal feed products pose significant concern to ORA as they have not been examined to determine compliance with FDA regulations.

ORA's Division of Food Defense Targeting, primary role is to protect U.S. consumers from an intentional threat or actual terrorist attack on the U.S. food and feed supply. In FY 2012, ORA performed more than 80,000 prior notice reviews of food and feed, leveraging advancements that were made to ORA's prior notice targeting and risk assessment processes through increased intelligence-related food and feed shipment data research.

In FY 2012, ORA awarded contracts and grants to state and local agencies to increase collaborative efforts, leverage existing resources and bolster an integrated feed safety system. These contracts and grants included:

- Tissue residue program contracts to states to provide for completion of tissue residue inspections by state inspectors
- Food Protection Task Force grants to state and local agencies
- Small Scientific Conference grants to associations to increase interactions to assure uniformity and consistency in enforcement activities
- Contracts and cooperative agreements awarded to states under the Feed Safety BSE program.

In FY 2012 ORA provided funding to state, local, tribal and territorial partners to support capacity building in the areas of recalls and inspections in support of Section 210 of FSMA. Several feed programs received funding under these cooperative agreements to build their capacity, capabilities and infrastructure in these critical areas.

ORA collaborated with CVM and the AAFCO to develop AFRPS. These standards are currently in review and, when issued, will provide uniformity and consistency among regulatory programs responsible for the inspection of feed facilities across the nation. These standards are a critical component of an integrated food safety system as envisioned by FSMA.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
242201: Review adverse experience reports to detect animal product hazards early. *(Output)*	FY 2012: 75% Target: 55% (Target Exceeded)	55%	80%	+25%

Strengthening Surveillance and Enforcement – B. Strengthening Enforcement - Center Activities

Base Amount: $9,325,000 (BA: $8,804,000 / UF: $521,000)

Public Health Focus and FDA Food Safety Strategy

CVM protects human and animal health by continuing to focus on developing and implementing appropriate enforcement strategies, such as inspections, and regulatory decisions that need to be in place to ensure the compliance of marketed products. Working with state counterparts, CVM conducts targeted, risk-based interventions with emphasis on the points of manufacture and distribution in order to prevent contaminated food and feed from entering the food supply.

CVM supports the *FVM Strategic Plan* goals of achieving high rates of compliance with preventive controls standards domestically and internationally, and advancing animal drug safety and effectiveness.

Public Health Outcome

CVM's program and regulatory actions aim at preventing illegal drug residues in human food products derived from animals improperly treated with drugs. CVM is committed to preventing violations and enforcing the FD&C Act and related laws through guidance, education and regulatory actions. CVM conducts a wide range of compliance activities designed to assure post-approval safety of new animal drugs and safety of all other products that are within CVM's regulatory sphere.

In July 2012, CVM developed criteria for identifying high risk firms for priority inspections under the FSMA mandate. In addition, FDA initiated a collaborative project with the Minneapolis District Office and states within the district to identify common elements for FDA and states when doing feed facility inspections.

CVM continues to use risk-based inspection criteria for the BSE, tissue residue, medicated feeds and animal drug inspection programs. These criteria allow CVM, in collaboration with ORA, to prioritize inspection workload based on risk. The risk-based inspections enable CVM and ORA to maximize resources for protecting human and animal food and animal drugs. CVM continues to gain experience with the new real-time Polymerase Chain Reaction method as the primary analytical method of testing imported and domestic animal feed and feed ingredients for the presence of BSE-related prohibited material.

Strengthening Surveillance and Enforcement – B. Strengthening Enforcement - Field Activities

Base Amount: $15,787,000 (BA: $12,598,000 / UF: $3,189,000)

Public Health Focus and FDA Food Safety Strategy

One of ORA's primary feed protection duties is to conduct risk-based inspections and enforcement activities. ORA investigators conduct physical inspections of regulated domestic and foreign feed establishments and conduct follow-up investigations on reports of tissue residues.

In the case of Strengthening Enforcement, ORA achieves the FSMA strategy by:

- Implementing new enforcement authorities designed to achieve higher rates of compliance with prevention and risk based food and feed safety standards
- Conducting risk-based domestic and foreign food and feed safety inspections
- Implementing new enforcement authorities
- Improving mechanisms for assuring that imported food and feed meet preventive controls standards
- Improving the collaboration with state, local, tribal and territorial officials and staff on inspection and compliance efforts.

By adopting risk-based approaches for conducting inspections, ORA can utilize scarce resources and maximize the public health benefit to consumers by ensuring higher rates of compliance.

Public Health Outcome

Currently, the best approach to improving the safety and security of feed is to utilize resources to expand targeting and follow through in potentially high-risk areas such as:

- Reviewing risk-based scenarios of bioterrorism and developing criteria that target food and feed ingredients that are at risk for intentional contamination
- Working in conjunction with CVM to take steps to reinstate the milk monitoring program including developing methods
- Creating and launching a searchable FDA webpage and database for recalls including a process and tracking system
- Implementing a new streamlined enforcement process for seizures and injunctions
- Issuing 76 warning letters to prevent the continued distribution of adulterated animal products into U.S. commerce
- Drafting a new Compliance Policy Guide describing policy for refusing imports of foods and medical products exported from facilities that have refused an FDA inspection
- Supporting the development of state infrastructure, territorial and tribal animal feed safety, and BSE prevention programs to assure a broader regulatory framework for the U.S. feed supply.

When firms are found to be operating in violation of FDA requirements of the FD&C Act, FDA takes regulatory action to assist them to come into compliance while ensuring that products of concern do not reach U.S. consumers. When firms refuse to comply with FDA regulations, FDA takes further enforcement action to ensure unsafe products do not reach U.S. consumers and works to request the firms potential shut down of operations.

In FY 2012, FDA issued several warning letters, injunctions and court decrees as a result of ORA recommendations for regulatory action based on violative inspection findings. In January 2012, ORA issued notices of shutdown and liquidated damages against two dairy farms for continued violations of consent decrees they had entered into with FDA. Neither location had implemented appropriate corrective actions to ensure they were operating in accordance with FDA regulations; however, both farms continued to operate.

ORA initiated an investigation into the manufacturing and marketing of two Type B medicated animal feeds used for show cattle in March 2012. The products posed a human safety concern when not handled in an appropriate manner; however, the products did not have a warning statement regarding human handling. Additional concerns existed given that show animals have a higher rate of handling by younger people. The investigation identified the manufacturers of the products and also uncovered that the products were manufactured at an unlicensed feed mill. ORA's investigation led to a recall of all feed lots manufactured in a two-year time frame.

When an imported product is found to be adulterated, misbranded, or otherwise not in compliance, it may be subject to refusal. A refused product must be exported or destroyed. In FY 2012, ORA refused more than 25,000 lines of FDA regulated products. To date, ORA refused over 350 lines of animal feed and drug products.

Submission of accurate prior notice data for imported food and feed shipments ensures that ORA can complete meaningful bio-security risk assessments. In FY 2012, ORA made more than 400 informed compliance calls to regulated trade due to incomplete or inaccurate prior notice data submissions. In addition, ORA initiated more than 700 compliance enforcement cases, in conjunction with CBP, where Bioterrorism Preparedness and Response Act of 2002 registration information was lacking. The inadequate prior notice data was so egregious that it restricted ORA's ability to perform meaningful risk assessments. These actions require resubmission of accurate prior notice data before the imported food and feed shipments are allowed to enter the U.S.

During FY 2012, there were four injunctions against farms that had offered for sale animals for slaughter found to be adulterated with drug residues. These actions protect consumers from exposure to these meats and require farms to meet these statutory and regulatory requirements.

During FY 2012, FDA classified 28 Class I (most serious); 26 Class II; and 13 Class III recalls of animal products regulated by FDA. These included recalls of pet food, animal feed, animal drugs and animal devices.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
244202: Number of domestic and foreign high-risk animal drug and feed inspections. *(Output)*	FY 2012: 271 Target: 250 (Target Exceeded)	250	250	Maintain
244203: Number of targeted prohibited material BSE inspections. *(Output)*	FY 2012: 548 Target: 500 (Target Exceeded)	500	500	Maintain
244204: Complete review and action on warning letters received within 15 working days to better safeguard our food supply by alerting firms to identified deviations in order to become compliant. *(Output)*	FY 2012: 66% w/in 15 working days Target: 50% w/in 15 working days (Target Exceeded)	50% w/in 15 working days	60% w/in 15 working days	+10%

Improving Response and Recovery – Center Activities
Base Amount: $2,225,000 (All BA)

Public Health Focus and FDA Food Safety Strategy

The requested resources will enable CVM to protect human health by implementing strategies for early detection of illnesses associated with food, tracing the source of the outbreak and removing the contaminated product from the market which is critical to containing potential risks to human and animal health.

CVM supports the *FVM Strategic Plan* goals of strengthening scientific leadership, capacity, and partnership to support public health and animal health decision making, and improving detection of and response to food-borne outbreaks and contamination incidents.

Public Health Outcome

As a requirement of FDAAA, CVM, in collaboration with CFSAN and other FDA offices, utilizes the Reportable Food Registry (RFR) to provide a reliable mechanism to track patterns of adulteration in food and feed. The RFR requires manufacturers, processors, packers and holders of FDA-regulated foods and feeds to quickly report to FDA via the online Safety Reporting Portal any foods, feeds or ingredients that could result in serious adverse health consequences to humans or animals. Reportable food submissions provide early warning to FDA about potential human and animal health risks and increase the speed with which FDA and its partners at the state and local

levels can investigate the reports and take appropriate follow-up action, including ensuring that the reportable human foods and animal foods are removed from commerce when necessary. In April 2012, the Second Annual Reportable Food Registry Report was posted on the internet that contained 1,153 entries that helped speed identification and investigation of potential health hazards in human food and animal food, including pet food. The report indicated that the RFR findings have spurred efforts to improve preventive measures in affected commodity areas, both by industry and FDA, and are helping FDA better target its inspection and sampling activities.

CVM continues to utilize the Veterinary-Laboratory Investigation and Response Network (Vet-LIRN) which integrates state and federal laboratories resources and expertise for timely and accurate reporting, identification, and analysis of animal feed chemical and microbiological contamination events. The system operates by examining animal tissues and diagnostic specimens for microbiological agents, toxins, and other causes of disease. In November 2011, Vet-LIRN began to lead CVM's testing program to investigate the root cause of pet jerky treat-associated illness. The activities included a meeting in China with the Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) for bilateral discussions and scientific collaborations on this issue.

In April 2012, Vet-LIRN also worked with the Coordinated Outbreak Response and Evaluation Network (CORE) on the recent *Salmonella infantis* outbreak. CVM laboratories were able to assist the Centers for Disease Control and Prevention (CDC) by testing pet samples from households with human patients, using collaborative agreement laboratories that had recently harmonized testing methods for this pathogen in canine feces. In FY 2012, the total number of collaborating laboratories rose from nine to 26. These efforts contribute to overall food safety as animal feed events could signal potential issues in the human food system.

In advance of foodborne illness events, CVM reviews and improves the protocol and roles and responsibilities for emergency coordination. This includes monitoring and responding, in real-time, to situations involving contaminated food and feed. As such, CVM is able to initiate a rapid FDA response upon detection and identification of an animal disease outbreak associated with pet food products. CVM also ensures that communications relating to food safety meet the health and information needs of consumers. Improving safety through better risk communication ensures consumers understand what to do – and not do – in response to safety problems.

Improving Response and Recovery – Field Activities
Base Amount: $9,851,000 (All BA)

Public Health Focus and FDA Food Safety Strategy

With the integrated food supply chain, it is more important than ever for ORA to work with its regulatory partners, specifically its federal, state, local, tribal and territorial partners, in order to protect the nation's food supply.

In the case of Improving Response and Recovery, ORA achieves the overall FDA strategy by

- Better responding to and containing problems when they occur
- Investigating and adopting of innovative technologies and processes to detect and investigate such events
- Enhancing the RFR and effective risk communications related to outbreaks and contamination incidents
- Responding to issues that occur across the farm-to-table continuum
- Analyzing outbreaks and lessons learned to improve FDA activities at the other stages.

Public Health Outcome

In April 2012, USDA's Animal and Plant Health Inspection Service (APHIS) confirmed a case of BSE in a dairy cow. FDA immediately began working with APHIS, the state and the CDC to investigate the incident. During the course of the investigation, ORA performed inspections at more than ten feed manufacture facilities and dairy farms who had handled the animal during its life. The ORA inspections determined that no deviances from FDA regulations had occurred in the products of the feed that would have led to the positive BSE finding. Additionally, further analysis of the animals' tissue by USDA determined that the form of BSE found in the animal was spontaneously forming and not related to food or feed practices. The quick and collaborative response of the state and federal agencies involved led to an expedited resolution of the incident. U.S. and global consumers were also reassured that domestic cattle and their by-products for human and animal consumption were safe for consumption.

In FY 2012, ORA responded to numerous incidents reported through the Safety Reporting Portal (SRP) regarding pet foods and animal feed. In November 2011, FDA began receiving numerous reports through the SRP indicating adverse health events in dogs. The submissions had a commonality of pets having consumed foreign-manufactured chicken jerky pet treats. ORA put in place an import sampling and analysis bulletin (Import Bulletin#: 72-B04) to allow for testing to identify potential causes of the adverse reactions. ORA investigators collected more than 50 samples which were analyzed for a variety of potential contaminants including melamine/cyanuric acid, ethylene glycol, diethylene glycol and propylene glycol. ORA developed improved methodologies to identify procedures to enhance the recovery and detection of the targeted contaminants. Additionally, ORA expedited the inspection of five foreign manufacturing facilities of suspect pet treats. ORA conducted the

inspections with foreign regulatory counterparts that led to a second tier of inspections of foreign-sourced ingredient suppliers. FDA continues to investigate this issue and has established a scientific working group to evaluate possible contaminant sources. As a result of ORA's import sampling bulletin, propylene glycol was detected in cat treats, a violation of FDA requirements of the FD&C Act. These findings led to the establishment of a new Import Alert to ensure no future shipments of products of concern gain entry into the U.S. market without assurance that they are in compliance with FDA regulations and safe for animal consumption.

ORA leverages its regulatory partnerships to rapidly respond to outbreaks and facility recovery. Examples of these partnerships include:

- State contracts
- Food Emergency Response Network (FERN) laboratories
- Rapid response cooperative agreements
- Customs Border Patrol (CBP)
- Food Protection Task Force grants
- BSE contracts and cooperative agreements
- 50-State Meetings.

ORA supports FERN, a network of state and local labs that perform laboratory analyses for FDA in the event of a public health emergency. FERN laboratories provide critical analytical surge capacity during food emergency events. The ability to rapidly test large numbers of samples of potentially contaminated food products is a critical component of controlling threats from deliberate foodborne contamination.

In FY 2012, ORA funded the expansion of the Rapid Response Team cooperative agreement with the inclusion of new states into the program in support of continued and widespread development of an all hazards response network for food and feed emergencies.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
244301: Total number of collaborating laboratories that will provide coordinated response to high priority chemical and microbial animal feed contamination events. *(Outcome)*	FY 2012: 23 Target: 23 ((Target Met)	23	26	+3

Animal Drug Review – Center Activities
Base Amount: $26,008,000 (BA: $16,344,000 / UF: $9,664,000)

Public Health Focus

The increasing companion animal population in the United States, along with the growing affinity pet owners have for their pets as evidenced by the rising expenditures for pet care and aggressive marketing of pet products, illustrates the need for more safe and effective drugs for disease prevention, treatment, and control in companion animals. CVM meets this public interest need by increasing the availability and diversity of approved, safe and effective veterinary products which relieve the pain and suffering of pets.

CVM's prioritizing prevention activities support the *FVM Strategic Plan* goals of strengthening scientific leadership, capacity, and partnership to support public health and animal health decision making, and advancing animal drug safety and effectiveness.

Public Health Outcome

Timely review for safety and effectiveness of new animal drug products is critical to bringing innovative, high quality, and safe medical products to market for companion animals. CVM reviews safety and effectiveness data submitted in premarket applications for pioneer and generic new animal drugs.

CVM employs a phased-in approach to minimize the likelihood that drug makers will make critical and costly mistakes that delay the review of new animal drugs, thus bringing safe and effective products to the market more efficiently. This approach encourages sponsors to submit information to support approval as it becomes available, rather than waiting until they have collected all needed information and to maintain ongoing consultations with CVM about requirements for approval.

In the area of regulatory research, CVM scientists are working on essential innovation methods research aimed at addressing new veterinary drug safety and efficacy challenges presented by cutting-edge medical technologies, such as stem cell therapies. CVM's stem cell research supports premarket drug review of animal stem cell products, a new category of animal drugs in terms of product characterization. The first stem cell research was performed at CVM to define stem cell markers in canine mesenchymal stem cell products derived from various tissue sources. The study will prepare CVM for future stem cell or other cellular product-related regulatory research.

Animal Drug Review – Field Activities
Base Amount: $2,600,000 (BA: $2,125,000 / UF: $475,000)

Public Health Focus

ORA Field supports the Animal Drugs and Feeds Program by advising FDA leadership on enforcement, import, inspection and laboratory policies. Through its Field offices nationwide, ORA supports the Animal Drugs and Feeds Program by conducting premarket inspections of domestic and foreign establishments to determine the safety and effectiveness of manufactured products.

Public Health Outcome

ORA's Field force conducts preapproval inspections to support CVM's review of premarket applications for pioneer and generic animal drugs. The Field inspects manufacturing establishments to determine their ability to manufacture the product to the specifications stated in their application. ORA performs inspections of non-clinical laboratories engaged in the collection of data to determine whether Good Laboratory Practices are followed. Accurate data is essential to the review and approval of new animal drugs. Inspections also help ensure that the rights and welfare of animals are protected.

Performance Measures

The Animal Drugs and Feeds Program is supported by the ADUFA and AGDUFA user fee programs. Under ADUFA and AGDUFA, FDA agreed to pursue a comprehensive set of animal drug review performance goals.

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
243201: Complete review and action on original New Animal Drug Applications (NADAs) and reactivations of such applications received during the fiscal year. *(Output)*	FY 2012: 100% w/in 180 days Target: 90% w/in 180 days (Target Exceeded)	90% w/in 180 days	90% w/in 180 days	Maintain
243202: Complete review and action on Non-administrative original Abbreviated New Animal Drug Applications (ANADAs) and reactivations of such applications received during the fiscal year. *(Output)*	FY 2011: 100% w/in 500 days Target: 90%w/in 500 days (Target Exceeded)	90% w/in 380 days	90% w/in 270 days	-110 days

Postmarket Safety and Compliance – Center Activities

Base Amount: $17,859,000 (All BA)

Public Health Focus

CVM monitors the safety and effectiveness of marketed animal drugs and devices in ensuring the health and safety of animals. Wider use of products often results in the discovery of problems not evident during the premarket review stage. Consequently, CVM's surveillance efforts enable the identification of potential harm prior to an adverse event. In addition, CVM is responsible for controlling the spread of zoonotic diseases that can be transmitted from animals to humans by pets and exotic animals.

CVM's Postmarket Safety and Compliance activities support the *FVM Strategic Plan* goals of strengthening scientific leadership, capacity, and partnership to support human and animal health decision making, providing accurate and useful information so consumers can choose a healthier diet and reduce the risk of chronic disease and obesity, and advancing animal drug safety and effectiveness.

Public Health Outcome and Accomplishments

As in the foods area, FDA has a human health objective of ensuring the safety of animal drugs throughout the life cycle. CVM utilizes and maintains an Adverse Drug Event (ADE) database to identify drug safety signals and effectiveness issues of concern that were not detected during pre-market testing. CVM scientists use the ADE database to make decisions about product safety, which may include changes to the label or other regulatory action. Early identification of unsafe and ineffective drugs through a robust surveillance system helps foster public assurance that FDA is working for their benefit by promoting confidence in the nation's drugs.
CVM compliance activities include working on emerging issues involving animal drugs and zoonotic diseases that require immediate CVM response and coordination. These issues may arise in relation to imports, consumer complaints, contamination incidents, emergencies and/or recalls. In addition, CVM coordinates enforcement actions against unapproved drugs that are on the market and that threaten animal health. Further, CVM regulates the promotion and advertising of animal drugs to make sure they are promoted in a truthful and non-misleading way.

CVM addresses regulatory issues designed to prevent and control the spread of zoonotic diseases, in both animal and human populations. This includes controlling the spread of infectious zoonotic diseases such as variant Creutzfeldt-Jakob disease, monkeypox, salmonellosis, and avian influenza. The constant interactions of humans, animals, and the environment have a tremendous impact on human health.

CVM's international activities have continued to grow in response to the increased globalization of the markets for CVM regulated products. CVM's International Programs Team (IPT) leads, coordinates and manages CVM's international activities in collaboration with relevant FDA Programs. IPT has adopted a strategic plan to enable CVM to better meet that challenge to advance the overall mission of CVM and FDA in an international context. As part of its work, IPT will use One Health strategies that

decrease the spread of zoonotic diseases and enhance the societal importance of the human-animal bond globally. The IPT will accomplish its mission by working with various strategic partners within and outside of FDA.

Postmarket Safety and Compliance – Field Activities
Base Amount: $2,686,000 (All BA)

Public Health Focus

ORA supports the Animal Drugs and Feeds Program by evaluating manufacturing practices to determine the safety and effectiveness of manufactured products. ORA also supports the Animal Drugs and Feeds Program by advising FDA leadership on enforcement, import, inspection and laboratory policies.

Public Health Outcome

Through its Field offices nationwide, ORA supports the Animal Drugs and Feeds Program by conducting postmarket inspections of domestic and foreign establishments to determine the safety and effectiveness of manufactured products.

ORA performs routine inspections of regulated industry to ensure compliance with FDA regulations. In FY 2012, ORA conducted more than 55 animal drug inspections in 14 different countries.

ORA monitors and samples imports to ensure the safety of the animal drug supply. In instances of criminal activity, ORA's Office of Criminal Investigations (OCI) and the Forensic Chemistry Center (FCC) complement the regular Field activities.

ORA supports CVM's evaluation of adverse event reports. The Field offices conduct follow-up inspections on adverse event reports when information from the manufacturer is needed to evaluate the risks involved. In addition, ORA reviews adverse events and complaint files during inspections for compliance with FDA reporting regulations. In the event of a public health incident concerning a disease from an animal, for example *Salmonella* from pet turtles, ORA assists CVM by conducting any appropriate investigations. Targeted inspections allow for efficient use of FDA resources while focusing efforts on products of concern that are destined for or may already be in the U.S. market.

During FY 2012, OCI made six Animal Drug related arrests and secured two convictions with fines. One such investigation concerned the introduction of an unapproved animal drug. In July, 2012, an internet company pled guilty to distributing unapproved animal medications throughout the United States. The canine medication was for heartworms and was not approved by FDA for use. This large internet distributor also imported various unapproved drugs that were advertised falsely for other medical conditions. The safety and supply of pet foods and products, like human foods, must be pure and

wholesome and contain no deleterious substances and be truthfully labeled. OCI's investigations into illegal activities related to animal drugs and products prevent and protect animals from dangerous unapproved medical treatment.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
242201: Review adverse experience reports to detect animal product hazards early. *(Output)*	FY 2011: 75% Target: 55% (Target Exceeded)	55%	80%	+25%

Information Technology Investments – Animal Drugs and Feeds Program Activities (Base Amount displayed as a non-add item: $19,359,306)

The following are CVM specific IT efforts related to the regulation of our nation's animal drugs, devices and additives used in animal feed:

- In an effort to support FDA-level, all electronic work environments initiative, CVM is expanding its Electronic Document Submission and Review system (EDSR) to include Drug Experience Reports and Minor Use Minor Species Drug Index Files. Currently, CVM uses EDSR for premarket new pioneer and generic animal drug applications and investigational files, food additive petitions, investigational food additive files, and Generally Recognized as Safe notifications. In addition, CVM continues to convert its paper archives into an electronic archive.
- CVM continues expanding and enhancing the electronic processing of adverse event reports to include voluntary animal drug event reports, medicated feed reports, and reportable food reports (both pet food and animal feed), which allows FDA ready access and efficient review of the reports to protect and promote human and animal health.
- CVM plans to initiate the development of an animal feed and pet food database to support the Food Safety Modernization Act (FSMA).
- CVM continues expanding and enhancing the National Antimicrobial Resistance Monitoring System (NARMS) with its external stakeholders including Centers for Disease Control and Prevention, the U.S. Department of Agriculture, and state agencies. This includes, initiating the expansion of the number of data entry points for state reporting laboratories, developing additional analytical tools for regulators and researchers, and expanding the user community to include states, academia, and research organizations.
- See Field section for Field IT activities supporting the Animal Drugs and Feeds Program.

Five Year Funding Table with FTE Totals

The following table displays funding and full time equivalent (FTE) staff levels from FY 2009 through FY 2013 for the Animal Drugs and Feeds Program.

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
FY 2010 Actual	$153,919,000	$134,360,000	$19,559,000	767
FY 2011 Actual	$158,771,000	$139,025,000	$19,746,000	806
FY 2012 Actual	$156,909,000	$137,964,000	$28,344,000	796
FY 2013 CR[1]	$166,268,000	$137,750,000	$28,518,000	825
FY 2014 Request	$190,753,000	$141,566,000	$49,187,000	864

[1] *Includes adjustments for the Food and Veterinary Medicine Program reorganization and reprogramming approved in FY 2012 that started in FY 2013: -8 FTE and -$1.109M in the Animal Drugs and Feeds Program.*

Summary of the Budget Request

The FY 2014 budget request for the Animal Drugs and Feeds Program is $190,753,000. This amount is an increase of $25,497,000 above the FY 2012 Enacted budget. The CVM amount in this request is $118,426,000, supporting 524 FTE. The Field amount is $72,327,000 supporting 340 FTE.

The base funding for the Animal Drugs and Feeds Program is $165,256,000, which includes $108,387,000 for the CVM activities and $56,869,000 for the Field activities.

Base funding allows the Animal Drugs and Feeds Program to meet its mission to protect human and animal health by increasing the availability and diversity of safe and effective products that relieve animal pain and suffering, sustain their health, improve food-producing animal productivity, and do not compromise human health. The program will support the evaluation, approval and post-approval monitoring of animal drugs, devices and additives used in animal feed. In addition, the funding will satisfy the trigger requirements for user fee collections under the Animal Drug User Fee Act (ADUFA) and the Animal Generic Drug User Fee Act (AGDUFA).

The initiatives proposed under the FY 2014 president's budget request support mission critical program activities and Presidential, HHS and FDA public health priorities such as the Transforming Food Safety initiative, which aims to protect patients by implementing the Food Safety Modernization Act (FSMA).

Budget Request Details

Pay Increase (Total Program: $598,000)

The request for $598,000 in total BA for the Animal Drugs and Feeds Program reflects a pay increase for Civilian and Commissioned Corps staff. CVM's portion of the increase is $365,000 and the Field's portion is $233,000.

Adjustment to Base (Total Program: -$383,000 / -2 FTE)

The budget request for $141,566,000 in total budget authority for the Animal Drugs and Feeds Program also reflects a reduction to the base of -$383,000 for FY 2014. The Center's portion of this reduction is -$235,000 and -1 FTE; the Field's portion of this reduction is -$148,000 and -1 FTE.

Prioritizing Prevention

Center Activities –
FY 2012 Enacted Base: $39,659,000 (BA: $25,164,000 / UF: $14,495,000)
FY 2014 Total Increase above Base: (+$5,093,000 / 13 FTE)
FY 2014 Increase above Base for Proposed User Fees (ADUFA): (+$904,000 / 3 FTE)
FY 2014 Increase above Base for Proposed User Fees (AGDUFA): (+$842,000 / 0 FTE)

FY 2014 Initiative Increases above Base:

Transforming Food Safety Initiative: Standards-setting for Food and Feed Safety (BA +$2,587,000 / 7 FTE and Proposed Food Facility Registration and Inspection UF +$760,000 / 3 FTE)

The budget authority funding in this initiative will enable CVM to develop and implement a preventive, risk-based system that fully addresses all aspects of manufacturing, packing and storing animal feed. CVM will develop regulations to encourage the animal feed industry to take necessary steps in preventing, eliminating or reducing to acceptable levels, potential risks to human and animal health, including steps to:

- Eliminate or control risks from feed hazards
- Establish regulatory limits for feed hazards
- Provide training and outreach to regulatory partners and industry.

FDA will also develop guidances and standards in the following priority areas:

- Safe production of food and animal feed
- Uniform hazard analysis standards
- Scientifically sound, risk-based controls for food, feed and dietary ingredients
- Food safety plans for food and feed facilities.

Regulations and guidances are important prevention-focused tools in FDA's efforts to improve food and feed safety. The more successful the system is in safely producing, processing, transporting and preparing foods and feeds, the safer the nation's food supply will be.

In addition, CVM will rely on user fee funding to develop and administrate preventive control-based inspection training to FDA and other federal, state, local, tribal, and territorial regulatory and public health partners. CVM will also conduct education activities for industry on new preventive control standards that are intended to prevent the contamination of animal food and feed to help ensure that feed products are safe for U.S. consumers.

Field Activities –
FY 2012 Enacted Base: $12,288,000 (BA: $12,288,000 / UF: $0)
FY 2014 Total Increase above Base: (+$1,256,000 / 3 FTE)

FY 2014 Initiative Increases above Base:

Transforming Food Safety Initiative: Integrated Food Safety System (Proposed Food Facility Registration and Inspection UF: +$240,000 / 1 FTE)
With this investment FDA will continue to develop and implement an integrated national food safety system built on uniform regulatory program standards, strong oversight of the food supply, and sustainable multi-year infrastructure investments to provide uniform coverage and safety oversight of the food supply. ORA will hire one FTE to serve as field state liaisons to assist the states implementation of the Animal Feed Regulatory Program Standards (AFRPS).

Transforming Food Safety Initiative: Standards-setting for Food and Feed Safety (Proposed Food Facility Registration and Inspection UF: +$538,000 / 0 FTE)
Investments will allow FDA to implement preventive controls in feed processing facilities. ORA will conduct the following activities with the resources:

- Support the implementation and enforcement of preventive controls in feed processing facilities
- Continue to train 215 inspection personnel – consisting of ORA inspection personnel, as well as a portion of FDA's state, tribal, and territorial regulatory partners – in preventive controls inspections and enforcement methods.

Transforming Food Safety Initiative: Import Safety: FSMA Outreach (Proposed Food Import UF: +$239,000 / 1 FTE)

With this investment FDA will hire one FTE to provide outreach and education on FSMA import provisions, including outreach to the import community and other federal agencies involved in the import process.

Transforming Food Safety Initiative: Import Safety: Quality Management (Proposed Food Import UF: +$239,000 / 1 FTE)
With this investment FDA will hire one FTE to implement a quality management system and quality control measures for the import review process at all locations and provide dedicated quality management measures to assess and assure the consistency of the import review process.

Strengthening Surveillance and Enforcement - A. Strengthening Surveillance

Center Activities –
FY 2012 Enacted Base: $13,311,000 (BA: $13,311,000 / UF: $0)
FY 2014 Total Increase above Base: (+$2,604,000 / 10 FTE)

FY 2014 Initiative Increases above Base:

Transforming Food Safety Initiative: Import Safety (Proposed Food Import UF +$1,439,000 / 6 FTE)
CVM will rely on user fee funding to establish new systems to prevent the import of unsafe feeds earlier in the process rather than detaining a product at the border. This will include assessments of feed safety systems in exporting countries for comparability to the U.S. feed safety systems. CVM will conduct outreach with international public health agencies to help establish international cooperation to ensure a safe feed supply. These resources will improve consumer protection by allowing FDA to make better informed decisions about the admissibility of imported food and feed products to ensure they are safe for U.S. consumers.

Transforming Food Safety Initiative: Risk Analysis: Develop and Validate Safety Risk Models (Proposed Food Facility Registration and Inspection UF +$380,000 / 1 FTE)

CVM will rely on user fee funding to collect, analyze, and manage risk data from a variety of sources, build the necessary decision tools, and outline the internal processes for systems-based approach enabling data-driven, evidence-based decision making. These funds will provide CVM with the ability to rank and prioritize food and feed safety concerns and identify how to apply CVM resources to achieve the best possible public health outcomes.

Transforming Food Safety Initiative: Domestic Inspections (Proposed Food Facility Registration and Inspection UF +$190,000 / 1 FTE)

CVM will conduct microbiological surveillance in strains such as *Salmonella* and monitor high priority commodities whose public health risk has yet to be ascertained, such as imported seafood, and animal feeds.

Transforming Food Safety Initiative: Science for Food Safety (BA +$595,000 / 2 FTE)

FDA will develop next generation methods to detect high priority contaminants in animal feeds and feed components. FDA will:

- Evaluate and customize commercially available systems to detect illegal drug residues in animal feed and animal derived products for human consumption
- Develop metabolism studies to identify marker residues used to develop and validate analytical methods to detect residues in imported and domestic animal feed
- Expand the technical capacity of its laboratory surveillance networks to analyze animal feed commodities for contamination.

Scientific research and analysis provide the basis for prevention and the development of appropriate regulations and guidance.

Field Activities –
FY 2012 Enacted Base: $13,657,000 (BA: $13,657,000 / UF: $0)
FY 2014 Total Increase above Base: (+$7,941,000 / 12 FTE)

FY 2014 Initiative Increases above Base:

Transforming Food Safety Initiative: Import Safety: Information Technology (IT): FSMA Implementation and FSMA Effectiveness (BA +$430,000 / 1 FTE)
With this IT investment, FDA will continue to improve the overall effectiveness of FSMA implementation by providing cross-cutting support to achieve all FVM Strategic Plan goals. FSMA IT investments allow FDA to capitalize on pre- and post-market data, scientific research, and current event information to more effectively prevent public health events and ensure the safety of the food supply from farm to table. IT tools, systems, and infrastructure allow FDA to improve and expedite the identification of threats to the public health, and ultimately reduce the occurrences of foodborne illness outbreaks. With these resources, FDA will conduct the following activities:

- Continue to make improvements needed to achieve more efficient information sharing among FSMA-related IT databases
- Develop, maintain, and evaluate data rules for food and feed products to begin targeting risk
- Develop data standards and methods to eliminate duplication and achieve efficiencies
- Employ technical project management and subject matter expert resources to manage and track the complex aspects of FSMA-related IT systems and databases and build critical FSMA institutional knowledge.

ORA will:

- Initiate integration of IT systems
- Begin targeting risk in PREDICT using other data sources as the data rules are completed.

Transforming Food Safety Initiative: Integrated Food Safety System (Proposed Food Facility Registration and Inspection UF $240,000 / 1 FTE)
With this investment FDA will continue to develop and implement an integrated national food safety system built on uniform regulatory program standards, strong oversight of the food supply, and sustainable multi-year infrastructure investments to provide more uniform coverage and safety oversight of the food supply. In this subprogram, ORA will hire one FTE to serve as a Scientific Coordinator to support the states as FDA moves to national standards for laboratories.

Transforming Food Safety Initiative: Import Safety: National Call Center (Proposed Food Import UF: +$717,000 / 3 FTE)

This investment will allow FDA to provide timely responses to inquiries concerning the import process or the status of imports by establishing a national call center. The call center will help meet FSMA requirement for industry assistance, improve overall compliance with FSMA rules, and reduce time to solve problems.

Transforming Food Safety Initiative: Import Safety: Expanded Port/Border (Proposed Food Import UF: +$4,490,000 / 6 FTE)

This investment will increase port/border coverage with more staff and longer hours of operation, thus providing better screening for food safety while also speeding up the overall entry admissibility process for safe products. Moreover, capital investments will be made to acquire additional space at various border locations to support this effort. This will result in increased efficiency, better industry/FDA communication, reduced time to resolve problems, and improved movement of trade.

Transforming Food Safety Initiative: Import Safety: Improving the Import Review Process (Proposed Food Import UF: +$2,064,000 / 1 FTE)

With this IT investment, FDA will improve information technology to enhance risk information and thus risk-based decision making for import personnel. IT tools, systems, and infrastructure allow FDA to improve and expedite the identification of threats to the public health, and ultimately reduce the incidence of foodborne illness outbreaks. With these resources, FDA will conduct the following activities:

- Hire one FTE to implement systems and IT changes to improve the consistency, predictability, and speed of the import review process, by working with industry to enhance the quality of data FDA receives.

- Utilize Remote Access Devices to allow field staff to examine shipments and complete all required electronic submissions for data entry on site, print labels for samples collected, and complete collection reports and all necessary documentation. In addition, expedited review, examination, and sampling of products will result in a decrease in the time needed to complete an inspection by providing field staff with the ability to perform the majority of work on site. The advanced technology will provide opportunities for enhanced targeting of shipments, resulting in greater assurance in the safety of commodities physically examined by FDA.

Strengthening Surveillance and Enforcement - B. Strengthening Enforcement

Center Activities –
FY 2012 Enacted Base: $9,325,000 (BA: $8,804,000 / UF: $521,000)
FY 2014 Total Increase above Base: (+$220,000 / 3 FTE)
FY 2014 Increase above Base for Current Law User Fees (Food and Feed Recall: (+$24,000 / 2 FTE)

FY 2014 Initiative Increases above Base:

Transforming Food Safety Initiative: Domestic Inspections (Proposed Food Facility Registration and Inspection UF +$196,000 / 1 FTE)

CVM will rely on user fee funding to modernize compliance programs and inspection practices to improve inspection efficiency by using the safety risk models to identify high risk firms and to prioritize firms for inspections and also the frequency of inspections. CVM will also use FDA's improved food safety enforcement tools and processes to support the prevention strategy mandated by FSMA.
With this increase, CVM can effectively:

- Provide oversight, ensure compliance, and respond effectively when problems emerge
- Achieve the most public health value from FDA inspections and compliance programs
- Successfully manage the increasing number of safety-related compliance cases expected in association with increased frequency of domestic inspections.

Field Activities –
FY 2012 Enacted Base: $15,787,000 (BA: $12,598,000 / UF: $3,189,000)
FY 2014 Total Increase above Base: (+$5,816,000 / 22 FTE)
FY 2014 Increase above Base for Current Law User Fees (Food Reinspection): (+$116,000 / 18 FTE)
FY 2014 Increase above Base for Current Law User Fees (Food and Feed Recall): (+$29,000 / 2 FTE)

FY 2014 Initiative Increases above Base:

Transforming Food Safety Initiative: Import Safety: Foreign Supplier Verification Program (Proposed Food Import UF: +$5,107,000 / 1 FTE)

This investment will support the implementation of the Foreign Supplier Verification Program (FSVP), which is a comprehensive prevention-focused import food and feed safety program that relies more heavily on those in the food supply chain – food and feed manufacturers, processors, packers, distributors, and importers – to provide assurances that the food and feed imported to the U.S. are safe and meet regulatory requirements.

Transforming Food Safety Initiative: Import Safety: Foreign Establishment Registration Verification (Proposed Food Import UF: +$564,000 / 1 FTE)

This investment will allow FDA to implement registration verification of foreign firms by conducting a foreign supplier verification program. Hire one FTE to provide program oversight.

Improving Response and Recovery

Center Activities –
FY 2012 Enacted Base: $2,225,000 (BA: $2,225,000 / UF: $0)
FY 2014 Total Increase above Base: (+$827,000 / 2 FTE)
FY 2014 Initiative Increases above Base:

Transforming Food Safety: Planning and Response (BA +$827,000 / 2 FTE)

CVM will develop a network of shared state, federal and other laboratory partners to investigate potential animal food and feed contamination events. CVM will also work with regulatory partners to close current gaps in the oversight of the animal food and feed industry. CVM will determine which laboratory accreditation options will best ensure that participating laboratories perform competent testing and provide consistent and meaningful data that will enable compliance with established FDA standards and make surveillance possible in partnership with the Veterinary Laboratory Investigation and Response Network (Vet-LIRN). Planning and responding effectively, when food safety problems emerge, will minimize negative public health impacts.

Field Activities –
FY 2012 Enacted Base: $9,851,000 (BA: $9,851,000 / UF: $0)
FY 2014 Total Increase above Base: ($0 / 0 FTE)

Animal Drug Review

Center Activities –
FY 2012 Enacted Base: $26,008,000 (BA: $16,344,000 / UF: $9,664,000)
FY 2014 Total Increase above Base: (+$1,165,000 / 2 FTE)
FY 2014 Increase above Base for Proposed User Fees (ADUFA): (+$603,000 / 2 FTE)
FY 2014 Increase above Base for Proposed User Fees (AGDUFA): (+$562,000 / 0 FTE)

Field Activities –
FY 2012 Enacted Base: $2,600,000 (BA: $2,125,000 / UF: $475,000)
FY 2014 Total Increase above Base: (+$217,000 / -1 FTE)
FY 2014 Increase above Base for Proposed User Fees (ADUFA): (+$157,000 / 0 FTE)
FY 2014 Increase above Base for Proposed User Fees (AGDUFA): (+$60,000 / 1 FTE

Post Market Safety and Compliance

Center Activities –
FY 2012 Enacted Base: $17,859,000 (BA: $17,859,000 / UF: $0)
FY 2014 Total Increase above Base: ($0 / 0 FTE)

Field Activities –
FY 2012 Enacted Base: $2,686,000 (BA: $2,686,000 / UF: $0)
FY 2014 Total Increase above Base: (+$143,000 / 1 FTE)
FY 2014 Increase above Base for Proposed User Fees (Medical Products Reinspection): (+$143,000 / 1 FTE)

Center Animal Drugs & Feeds Program Activity Data (PAD)			
Animal Drugs & Feeds Workload and Outputs	**FY 2012 Actuals**	**FY 2013 Estimate**	**FY 2014 Request**
New Animal Drug Applications (NADAs) [1]			
Received	14	13	14
Completed	13	13	14
Approved	11	12	13
Pending [2]	2	2	2
New Animal Drug Application Supplements [1, 3]			
Received	417	557	560
Completed	458	563	565
Approved	386	350	375
Pending [2]	101	95	90
Abbreviated New Animal Drug Applications (ANADAs) [1]			
Received	37	27	29
Completed	26	28	27
Approved	8	10	7
Pending [2]	29	28	30
Abbreviated New Animal Drug Application Supplements [1, 3]			
Received	177	190	195
Completed	221	198	200
Approved	171	114	125
Pending [2]	82	74	69
Investigational New Animal Drug (INAD) Files [4]			
Received	2,372	2,915	2,995
Completed	2,388	2,917	2,987
Pending [2]	345	343	351
Generic Investigational New Animal Drug (JINAD) Files [4]			
Received	304	245	258
Completed	305	240	260
Pending [2]	56	61	59
Food (Animal) Additive Petitions Completed	42	45	65
Investigational Food Additive Petitions Completed	106	95	115
Adverse Experience Reports (AERs) [5]			
Received	N/A	N/A	N/A
Reviewed	N/A	N/A	N/A
Adverse Drug Event (ADE) [6] **-- New Measure**			
ADE Reports Received	73,406	70,000	73,000
Post-Approval ADE Data Reviews	75	60	70

[1]Includes originals applications and reactivations. If the application is not approvable, the sponsor may submit additional information until FDA is able to approve the application.

[2]Reflects submissions received during the fiscal year that still require review.

[3]A supplemental application is a sponsor request to change the conditions of the existing approval. Supplemental applications can be significant (such as a new species or indication), or routine (such as product manufacturing changes). The estimates do not include invited labeling change supplement applications because it is not possible to accurately project sponsor or CVM requests for this type of application.

[4]An INAD or JINAD file is established at the request of the sponsor to archive all sponsor submissions for a phased drug review including requests for interstate shipment of an unapproved drug for study, protocls, technical sections, data sets, meeting requests, memos of conference, and other information.

[5]Retired in FY 2012.

[6] This is a new measure that will track the number of "Post-approval ADE data reviews" completed each fiscal year. A Post-approval ADE Data Review is a comprehensive report by product of multiple ADE reports (in some cases this could be hundreds or thousands of individual reports).

Devices and Radiological Health

The following table displays the funding and full time equivalent (FTE) staffing levels for FY 2012 through FY 2014.

FDA Program Resources Table
(Dollars in Thousands)

	FY 2012 Enacted	FY 2012 Actuals	FY 2013 [1] CR	FY 2014 Request	FY 2014 +/- FY 2012
Program Level	**$375,989**	**$390,954**	**$378,174**	**$435,046**	**$59,057**
Center	$280,655	$299,026	$282,336	$332,247	$51,592
FTE	1,374	1,510	1,530	1,503	-7
Field	$95,334	$91,928	$95,838	$102,799	$7,465
FTE	492	476	483	523	47
Program Level FTE	**1,866**	**1,986**	**2,013**	**2,026**	**40**
Budget Authority	**$322,672**	**$322,636**	**$324,647**	**$320,544**	**-$2,128**
Center	$241,475	$241,443	$242,953	$240,064	-$1,411
Field	$81,197	$81,193	$81,694	$80,480	-$717
Budget Authority FTE	**1,611**	**1,609**	**1,636**	**1,582**	**(27)**
Center	1,139	1,154	1,174	1,116	(38)
Field	472	455	462	466	11
User Fees	**$53,317**	**$68,318**	**$53,527**	**$114,502**	**$61,185**
Center MDUFMA	$33,177	$52,461	$33,380	$86,180	$53,003
FTE	209	325	325	356	31
Field MDUFMA	$1,060	$1,600	$1,067	$1,913	$853
FTE	12	13	13	10	-3
Center MQSA	$6,003	$5,122	$6,003	$6,003	$0
FTE	26	31	31	31	0
Field MQSA	$13,077	$9,135	$13,077	$13,077	$0
FTE	8	8	8	8	0
Field Medical Prod Reinspection [2]	$0	$0	$0	$3,651	$3,651
FTE	0	0	0	24	24
Field International Courier [2]	0	0	0	$3,678	$3,678
FTE	0	0	0	15	15
User Fees FTE	**255**	**377**	**377**	**444**	**67**

[1] Spending authority has been adjusted pursuant to PL 112-175, Section 101(c) for the applicable user fee programs.
[2] Proposed user fee

The FDA Devices and Radiological Health Program implements and enforces the following legal authorities:

Federal Food, Drug, and Cosmetic Act[1] (21 U.S.C. 321-399)
Radiation Control for Health & Safety Act (21 U.S.C. 360hh-360ss)
Medical Device Amendments of 1976[1]
Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 201)
Safe Medical Devices Act of 1990[1]
Mammography Quality Standards Act of 1992 (42 U.S.C. 263b)
Medical Device Amendments of 1992[1]

Food and Drug Administration Modernization Act[1]
Medical Device User Fee and Modernization Act of 2002[1]
Project Bioshield Act of 2004 (21 U.S.C. 360bbb-3)
Medical Device User Fee Stabilization Act of 2005[1]
Food and Drug Administration Amendments Act of 2007 (FDAAA)[1]
Patient Protection and Affordable Care Act, 2010
FDA Safety and Innovation Act (FDASIA), 2012[1]

Allocation Method: Direct Federal/Intramural

Program Description and Accomplishments

The Devices and Radiological Health Program (the Devices Program) began in 1976 with the passage of the Medical Device Amendments to the Food, Drug, and Cosmetic Act (the Act). The program operates with appropriations and user fees.

The Devices Program is responsible for the regulation of all medical devices, from simple articles such as tongue depressors to complex robotic equipment for surgery and cutting-edge diagnostic products such as implantable defibrillators. To protect the public from unnecessary exposure to radiation, the Devices Program also regulates radiation-emitting products that include microwave ovens, X-ray equipment, and medical ultrasound and MRI machines. In addition, the program monitors mammography facilities to make sure the equipment is safe and properly run.

Under the Devices Program, the mission of the Center for Devices and Radiological Health (CDRH) is to protect and promote the public health. CDRH assures that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. CDRH provides consumers, patients, their caregivers, and providers with understandable and accessible science-based information about the products it oversees. CDRH facilitates medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and assuring consumer confidence in devices marketed in the United States.

The Office of Regulatory Affairs (ORA) supports the Devices Program by assessing industry compliance with applicable regulations. To provide this support, ORA conducts premarket and postmarket inspections of domestic and foreign manufacturers. ORA also investigates medical device reports (MDR) and consumer complaints, monitors and evaluates compliance with recalls of violative products, and evaluates imports of medical devices and radiological products to ensure products meet FDA quality standards.
The Devices Program executes its regulatory responsibilities in five subprogram areas:

[1] Authorities under this act do not appear in sequence in the U.S. Code. The authorities are codified in scattered sections of 21 U.S.C.

☐ Premarket Device Review
☐ Postmarket Safety
☐ Compliance, Enforcement and Radiation Safety
☐ Device Innovation and Regulatory Science
☐ Mammography Quality Standards Act (MQSA)

Premarket Device Review – Center Activities
Base Amount: $143,183,421 (BA: $119,291,291 / UF: $23,892,130)

Public Health Focus

CDRH's Premarket Device Review activities focus on ensuring the safety and effectiveness of new devices and radiological products before they can be marketed in the United States. By increasing the predictability, consistency, and transparency of its premarket review programs, CDRH works to provide new treatments and diagnostic tests to American patients more quickly and to stimulate investment in and development of promising new technologies to meet critical public health needs.

Public Health Outcome

CDRH evaluates the safety and effectiveness of new devices and approves or clears thousands of products annually, many of which are critical to the delivery of health care in the United States. Recent examples of device approvals include the following:

- An externally worn glucose sensor that continuously measures glucose values and provides blood glucose trending information in real-time;
- The first DNA test to help health care professionals gauge the progress of anti-viral treatment in patients with solid organ transplants including the heart and lungs;
- The first heart defibrillator implanted under the skin instead of connected directly to the heart, designed to help restore regular heart rhythm.

In January 2011, CDRH announced a Plan of Action for 510(k) and Science to modernize and improve its premarket review of medical devices. The 2011 Plan of Action includes 36 specific actions, some of which actually began in 2010, that were designed to increase the predictability, consistency, transparency, efficiency, and timeliness of device premarket reviews. In the two years since FDA began implementing the plan, the speed and predictability of device review have improved for the first time in almost a decade, including significant reductions in the time it takes CDRH to review applications and the size of application backlogs.

Since CDRH began implementing the Plan of Action for 510(k) and Science, almost every major indicator has reversed and is now pointing in the right direction. CDRH has met almost all of its early implementation timelines. As implementation continues and the impact of the Plan grows over the next several years combined with additional

resources provided from reauthorization of the Medical Device User Fee Act, CDRH expects its performance on review times and reductions in backlogs to continue to improve. A detailed November 2012 report informing constituents of many actions CDRH is undertaking is available online.[35]

As CDRH continues to move forward with its ongoing premarket program improvements, CDRH is also in the process of implementing several new authorities from the FDA Safety and Innovation Act (FDASIA) that were signed into law July 9, 2012. Some of the changes complement steps CDRH has already taken to improve its premarket programs. These new authorities will change the way CDRH approves clinical trials, shortens timeline for scheduling appeals and issuing decisions, provides a new de novo pathway for risk-based classification of devices, and changes the process for the reclassification of devices.

CDRH is in the process of issuing new standard operating procedures, training staff, and developing a series of guidance documents that help explain and implement key provisions of FDASIA. It is important to note that under the new law, CDRH decisions will continue to be based on strong science. The public can find more information on FDA's website.[36]

The many improvements CDRH is undertaking include developing a range of updated and new guidance documents to clarify FDA requirements for timely and consistent product review. These efforts include:

- **Benefit-Risk Determinations.** On March 27, 2012, CDRH issued guidance clarifying the criteria used to make benefit-risk determinations a part of device premarket decisions. This guidance will provide greater predictability and consistency and applies a more patient-centric approach by considering patients' tolerance for risk in appropriate cases.
- **Artificial Pancreas Device System.** On November 9, 2012, CDRH issued final guidance to facilitate the development and marketing of Artificial Pancreas Device Systems (APDS) and to provide maximum flexibility to manufacturers seeking to bring this device to U.S. patients.
- **Electronic Copy Program**. On December 31, 2012, CDRH issued final guidance explaining the new Electronic Copy (eCopy) Program for medical device submissions. The eCopy Program is expected to improve the efficiency of the review process by allowing for the immediate availability of an electronic submission for review.

Bringing breakthrough medical devices to patients quickly, safely and effectively

[35] Available at: http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm329008.htm

[36] Available at http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/default.htm

improves lives and health care. To help this process, CDRH created the Innovation Pathway – a priority program for technologies that address unmet medical needs in

disease treatment, diagnosis and health care delivery. In FY 2012 CDRH launched Innovation Pathway 2.0, which offers new tools and methods to deepen collaboration between the FDA and innovators.

The Innovation Pathway 2.0 was built through CDRH's Entrepreneurs in Residence (EIR) program. The EIR program brings leaders in medical device development, health care, patient advocacy, business process improvement, decision science, venture capital investment, and information technology to work alongside agency staff and leadership. In October, 2012, CDRH launched its second cohort of Entrepreneurs in Residence, with the goals of improving other phases of the innovation ecosystem, including reducing the time and cost of clinical trials, streamlining the pathway from device approval to reimbursement, and striking the right balance between premarket and postmarket requirements. CDRH's Entrepreneurs in Residence program is part of the Strategy for American Innovation, a White House priority.

On January 12, 2012, CDRH announced the Innovation Challenge – a pilot program for innovative devices that address end-stage renal disease (ESRD). Three products for patients with ESRD were chosen to participate, including two implantable devices and a wearable artificial kidney. By July 2012, all three products had entered into the Collaboration Phase, producing a roadmap outlining the regulatory and scientific issues that need to be addressed. This focused effort will allow CDRH to assess the strengths and weaknesses of the Pathway's features and fine-tune them for broader adoption. The public can find more information on FDA's website.[37]

CDRH continues exploring other ways to reduce regulatory burdens on industry and expedite patient access to medical devices. In FY 2012 FDA launched a "parallel review" pilot program, where CDRH and the Centers for Medicare & Medicaid Services (CMS) will conduct concurrent review of medical devices for FDA approval and Medicare coverage. Under the pilot program CDRH and CMS collaborated with the manufacturer of a colorectal cancer screening test to facilitate the design of a clinical trial to satisfy the data requirements of both agencies. The two agencies will conduct independent review of the application while sharing analytical and clinical performance data. This process will provide significant cost savings to manufacturers and shorten the time it takes to bring important medical devices to American patients.

Premarket Device Review – Field Activities
Base Amount: $8,465,000 (BA: $7,457,000 / UF: $1,008,000)

Public Health Focus

[37] Available at:http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHInnovation/InnovationPathway/default.htm

The ORA Field force supports the Devices Program in the initial phases of the total product life cycle by conducting preapproval inspections of domestic and foreign establishments to determine if facilities are able to manufacture products according to the specifications stated in their applications. ORA also conducts bioresearch monitoring (BIMO) inspections of clinical research studies to safeguard patients and to validate laboratory methods for device premarket application decisions.

Public Health Outcome

ORA inspections ensure that medical device establishments are able to manufacture products according to the specifications outlined in an application and that concerns or issues raised during review of the application are accounted for. ORA efforts help to assure that medical products are cleared or approved based on reliable data and evidence of manufacturing capability, and once manufactured, become a viable supply of safe commodities for U.S. consumers.

ORA conducts inspections of clinical investigators, sponsors, contract research organizations, and monitors during Good Clinical Practice (GCP) BIMO inspections. These inspections serve to assess compliance with FDA's regulations governing the conduct of clinical trials, and to verify the accuracy and reliability of clinical trial data submitted to FDA in support of research or marketing applications. ORA also inspects Institutional Review Boards (IRBs), the main objectives of which is to protect the rights, safety and welfare of subjects involved in clinical trials of FDA-regulated products. During FY 2012, twenty GCP BIMO inspections resulted in findings of serious violations of FDA regulations that included inadequate protection of the rights, safety, and welfare of subjects in investigational studies.

CDRH provides ORA investigators with information on the use of the device being studied, previous clinical trials, and concerns raised during review of preapproval inspections. This collaboration with CDRH ensures that ORA field staff conduct the most efficient bioresearch monitoring inspections possible by focusing available inspection resources on significant issues related to data integrity and human subject protection. By doing so, FDA helps ensure that sponsors collect data that can support a device application rather than conducting clinical trials that yield data that cannot support approval.

In 2012, ORA worked with CDRH to execute a pilot program designed to increase efficiency for reviews of inspectional findings related to pre-clearance 510(k) violations. This pilot encourages early collaboration between the field and center to more quickly determine whether regulatory action is required to correct deficiencies observed during inspections. The expected outcome of the pilot is speedier review of inspectional findings and more efficient and quicker issuance of Warning Letters, if appropriate. As the pilot continues, ORA and CDRH are assessing the results, have made enhancements to internal communications, and have made efficiencies in compliance

timeframes. The result of more rapid decision-making and communication with manufacturers is swifter compliance action by industry and improved public health protection.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
253203: Percentage of received Original Premarket Approval (PMA), Panel-track PMA Supplement, and Premarket Report Submissions reviewed and decided upon. *(Outcome)*	FY 2010 [1/]: 79% in 180 days and 96% in 295 days Target: 60% in 180 days and 90% in 295 days (Target Exceeded)	60% in 180 days and 90% in 295 days	80% in 180 days [2/3/]	+20% in 180 days
253204: Percentage of 180 day PMA supplements reviewed and decided upon within 180 days. *(Outcome)*	FY 2011 [1/]: 95% in 180 days and 100% in 210 days Target: 85% in 180 days and 95% in 210 days (Target Exceeded)	85% in 180 days and 95% in 210 days	90% in 180 days [2/]	+5% in 180 days
253205: Percentage of 510(k)s (Premarket Notifications) reviewed and decided upon within 90 days. *(Outcome)*	FY 2011 [1/]: 95% in 90 days and 99% in 150 days Target: 90% in 90 days and 98% in 150 days (Target Exceeded)	90% in 90 days and 98% in 150 days	93% in 90 days [2/]	+3% in 90 days
253201: Number of Medical Device Bioresearch Monitoring (BIMO) inspections. *(Output)*	FY 2012: 305 Target: 300 (Target Exceeded)	300	300	Maintain

[1/] Premarket performance data reflects action through December 31, 2012. FY 2011 results are not final for measure 253203.

[2/] FY 2014 Premarket performance targets reflect performance commitments included in the Food and Drug Administration Safety and Innovation Act (FDASIA)

[3/] Target for applications that do not require Advisory Committee input. For complete goal and target information, refer to the MDUFA performance report.

Postmarket Safety – Center Activities

Base Amount: $39,115,099 (BA: $35,150,896 / UF: $3,964,204)

Public Health Focus

CDRH Postmarket Safety activities focus on monitoring medical device and radiological product performance – including adverse events – once the products reach market. CDRH analyzes safety signals with potential clinical impact, and when an issue surfaces, it strives to respond quickly to identify and limit potential public health problems. These efforts are critical to ensuring that devices and radiological products remain safe and effective for patients and consumers.

Public Health Outcome

In September 2012, CDRH made available for public comment a preliminary report entitled "Strengthening Our National System for Medical Device Postmarket Surveillance". This report proposes a strategy to establish a National Medical Device Postmarket Surveillance System. The report is available on FDA's website.[38]

The report proposes four specific actions, using existing resources and under current authorities, to establish this system:

- Establish a unique device identification system and promote its incorporation into electronic health information
- Promote the development of national and international device registries for selected products
- Modernize adverse event reporting and analysis
- Develop and use new methods for evidence generation, synthesis and appraisal.

CDRH's proposed strategic changes are intended to complement existing programs. Currently CDRH uses two principle systems to capture device-related adverse event and product problem reports: the Medical Device Reporting (MDR) System and the Medical Product Safety Network (MedSun).

CDRH receives more than 400,000 individual medical device reports annually from manufacturers, importers, distributors, user facilities, and voluntary reporters. Incidents in which a device may have caused or contributed to a death or serious injury, or experienced a malfunction must be reported to CDRH under the MDR program. CDRH carefully evaluates the reports received to identify safety concerns of public health importance.

While FDA continues to receive paper-based MDR reports, CDRH encourages manufacturers to submit medical device reports electronically in advance of regulation requiring mandatory electronic submission of MDR. Electronic medical

[38] Available at http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm301912.htm

device reporting (eMDR) provides significant cost savings to taxpayers and industry by replacing a far less efficient paper-based reporting system that requires manual database entry. As a result of CDRH's active industry engagement and outreach, the Center receives approximately 70 percent of MDR submissions electronically.

MedSun is an "active" adverse event reporting program that allows FDA to work collaboratively with the clinical community to identify, understand and solve problems associated with the use of medical devices. MedSun provides a better understanding of how certain devices are used in the clinical environment, how regulatory actions against manufacturers will affect patient care in hospitals and if manufacturer recalls and other actions successfully solved the reported device problems. In FY 2012, there were 21 recalls and 57 manufacturer actions directly influenced by MedSun reports.

CDRH uses Post-Approval Studies (PAS) to address postmarket device performance. With PAS, CDRH evaluates device performance and potential problems with high-risk devices used more widely and over a longer period of time than in clinical trials. Since the start of calendar year (CY) 2012, CDRH has more than 250 post-approval studies cited on FDA's website. Greater access to information about the scope, progress and results of PAS studies provide health care professionals, patients, and the public with an improved understanding of the performance of high-risk devices after they have been marketed. The public can find more information on FDA's website.[39]

CDRH collaborates with key stakeholders to develop registry systems that collect and maintain structured records on a specific device or disease and can be used as a vehicle to fulfill post-approval requirements in a least burdensome approach. Recently CDRH worked closely with public and private partners to develop a National Transcatheter Aortic Valve Replacement (TAVR) Registry. In FY 2012, the registry became ready for data collection. The goal of this multi-stakeholder registry is to provide sufficient information about the heart valve replacement for clinical quality measures and to simultaneously provide adequate data for both regulatory and coverage postmarket requirements.

Key infrastructure improvements, such as the establishment of the Unique Device Identification (UDI) System and the incorporation of UDI into health-related electronic records, will have a positive impact on the nation's ability to adequately monitor medical devices in the post-market period while reducing premarket data needs for some devices.

In FY 2012, CDRH published a proposed rule to require most medical device manufacturers to place a UDI on a label or the device itself. The proposed rule, whose comment period closed November 7, 2012, builds upon current standards and systems and reflects input CDRH received from industry, health care providers, and patients. In FY 2012, CDRH completed the initial design, development, and user acceptance testing

[39] Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma_pas.cfm

of the UDI Database (UDID), which will be used to receive, store, and access all of the UDI data.

Postmarket Safety – Field Activities
Base Amount: $791,000 (BA: $739,000 / UF: $52,000)

Public Health Focus

The ORA Field force supports the Devices Program in postmarket safety by conducting follow-up investigations of MDRs. These ORA inspections of reporting medical facilities and manufacturers identify significant problems by analyzing recurring problems and performing trend analysis. ORA also collects data on complaints, significant problems and potential hazards so corrective actions can be initiated. ORA conducts bioresearch monitoring inspections of post-approval studies to monitor the postmarket safety of products already available for public use.

Public Health Outcome

ORA conducts inspections of both domestic and foreign medical device firms on a periodic basis for surveillance purposes and on a for-cause basis when issues or concerns are identified. These inspections help to ensure the marketplace is safe from defective or hazardous products.

In FY 2012, ORA inspected the manufacturer of a gel product that is used during endoscopy procedures and was implicated in bacterial infections at a hospital. Samples collected from the inspection were analyzed by ORA Scientists and were found to be contaminated with multiple organisms. The inspection findings led to multiple lots of the products being recalled by the firm. ORA's activities ensured that products of concern were removed from the market and not a threat to U.S. patients.

FDA worked in FY 2012 with Customs and Border Protection/Laboratory Science Service when that agency detected passengers returning to the United States with elevated gamma radiation readings. Interviews with passengers disclosed that each had undergone a recent Positron Emission Tomography (PET) scan. Working with scientists at Los Alamos Laboratories, ORA investigated the clinics where these patients had undergone the procedures and identified the manufacturer of the radiological drug products. Inspections of the manufacturer identified numerous current good manufacturing practice (cGMP) deficiencies and potential leakage of radiological products. The inspection resulted in the firm's recall of the drug product and removal of the over-exposure potential from the public.

Additionally in FY 2012, ORA and CDRH collaborated to develop a pilot program intended to provide FDA with the capability of receiving 3rd party audit reports on medical device manufacturers. The objective of the pilot is to provide FDA with additional information related to the compliance status of manufacturers, thus

expanding FDA's knowledge of regulated industry when ORA and CDRH are identifying manufacturers for routine surveillance inspections. FDA will still perform for-cause inspections when warranted. In implementing and assessing this pilot, FDA aims to have increased information with which to perform its risk-based work planning, allow for greater efficiency in FDA's use of resources, and provide broader understanding of regulated industry. This program will lead to greater regulatory and consumer confidence in the medical device supply chain and allow for safe and effective medical device products for the U.S. market.

ORA is also engaged in the HHS Million Hearts Campaign. ORA investigators and laboratories, in collaboration with CDRH, have performed inspections of firms manufacturing stationary blood pressure monitoring stations used in retail pharmacies, imported blood pressure cuffs, and automated external defibrillators, and has initiated projects to develop analytical methods to assess the accuracy, reliability and effectiveness of these devices.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
252202: Enroll the top 15 MDR reporters by volume in the voluntary eMDR (Medical Device Reporting) program. *(Outcome)*	FY 2012: 87% Target: 87% (Target Met)	87%	NA	NA
252203: Percent of total received Code Blue MDRs [1/] reviewed within 72 hours during the year. *(Output)*	FY 2012: 90% Target: 90% (Target Met)	90%	90%	Maintain

[1/] Code Blue MDRs are defined as high priority MDRs based on criteria including but not limited to: pediatric deaths, multiple deaths and serious injuries, device explosions, and electrocutions

Compliance, Enforcement, and Radiation Safety – Center Activities

Base Amount: $35,560,040 (BA: $35,560,040 / UF: $0)

Public Health Focus

CDRH's Compliance, Enforcement, and Radiation Safety activities focus on protecting patient safety by assuring that manufacturers comply with laws and regulations intended to protect public safety. Ensuring manufacturer compliance helps assure the safety and efficacy of devices and protects consumer confidence in U.S. medical products worldwide.

Public Health Outcome

Compliance, Enforcement, and Radiation Safety activities are designed to quickly identify major violations and take prompt, clear and appropriate actions to resolve issues before they have widespread negative impacts on public health. Examples of recent compliance efforts include the following:

- On August 13, 2012, FDA initiated a recall on anesthesia delivery system devices for possible gasket leakage, which could cause an interruption of or inadequate patient anesthesia, temporary or permanent patient injury, or death.
- On October 12, 2012, FDA issued a warning letter to a manufacture of sterile medical devices after an FDA inspection revealed that the firm's validation of its sterilization method was inadequate.

CDRH's strategic and targeted compliance efforts are essential to maximizing the value of limited resources. During FY 2012, CDRH has been conducting in-depth, risk-based inspections of two device categories that historically have been responsible for a disproportionate share of public health issues: physiological patient monitors and ultrasonic surgical instruments. As a result of these evaluations, CDRH has already found approximately three times the normal rate of deficient quality systems at the manufacturing facilities. CDRH will work closely with industry to ensure device quality by informing the firms of inspectional observations and by re-inspecting to confirm that quality systems violations are addressed appropriately.

CDRH continues its Recall Process Improvement project to advance the clarity and timeliness of actions involving medical device firms whose products violate the Food, Drug and Cosmetic Act. In FY 2012, recall classification process improvements have increased the proportion of recalls classified on-time from 52 percent in 2011 to 84 percent in 2012, a 32 percent increase. By streamlining the recall classification process, CDRH is able to more rapidly resolve public health risks and better protect patients from devices that are defective.

To leverage limited inspection and compliance resources and lower costs to industry and taxpayers, in November 2012 CDRH joined an international coalition of regulatory authorities, including Australia, Brazil and Canada, to establish a Medical Device Single Audit Program (MDSAP). The MDSAP will allow a single regulatory audit of a medical device manufacturer to satisfy the needs of multiple regulatory jurisdictions. In FY 2012, CDRH participated in the establishment of a Regulatory Authority Council and the development of a draft Accelerated Project Plan. CDRH's participation helped define the deliverables and timelines necessary to launch the Pilot Study of the program. MDSAP will provide significant cost savings to American taxpayers and industry by eliminating duplicate inspections by trusted regulatory counterparts and by enabling a single, shared audit under one uniform regulatory standard.
On October 31, 2011, CDRH began the Case for Quality Initiative and released the "Understanding Barriers to Medical Device Quality" report to better define high-impact

quality manufacturing practices. The report describes many of the barriers that device manufacturers face in integrating best-quality manufacturing practices across their organizations, details several reasons for the barriers, and recommends steps to overcome them. In FY 2012, CDRH engaged industry to discuss timelines for short and long-term goals, mechanisms for stakeholder involvement and plans for how this initiative will be implemented at the national and regional levels. The report is available on the FDA website.[40]

Under the Radiological Health Program, CDRH administers the Electronic Product Radiation Control provisions of the FD&C Act to address current public health needs related to electronic product radiation. CDRH monitors radiation doses and industry's compliance with performance standards to reduce the incidence of and severity of radiation injury. As of October 2012, CDRH continues to exceed its 60 day performance goal for review of field establishment inspection reports. As of October 2012, 86 percent of field establishment inspection reports were reviewed within 60 days, a 10 percent improvement from CY 2011 performance level. This high level of performance permits more timely communication and rapid correction of deficiencies in radiation emitting electronic products and devices.

In May 2012 as part of FDA's Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging, CDRH released draft guidance titled Device Improvements for Pediatric X-ray Imaging. The purpose of the guidance is to encourage manufacturers to consider radiation safety of pediatric populations in the design of X-ray imaging devices. CDRH held a public meeting in July 2012 to receive feedback on the guidance. The public can find more information on FDA's website.[41]

CDRH continues to proactively assist the medical device sector to efficiently deploy resources by providing interactive, high-quality responses to thousands of industry questions concerning device and radiological health regulatory issues. These efforts include CDRH Learn, a comprehensive, interactive, and easily accessible online training resource available in multiple languages. In FY 2012, CDRH responded to over 29,000 inquiries from industry, and the CDRH Learn webpage was visited more than 430,000 times.

Compliance, Enforcement, and Radiation Safety – Field Activities
Base Amount: $68,474,000 (BA: $68,474,000 / UF: $0)

Public Health Focus

The ORA Field force supports the Device Program by advising FDA leadership on enforcement, import, inspection, and laboratory policies. Through its nationwide field offices and laboratories, ORA supports Compliance, Enforcement and Radiation Safety

[40] Available at http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM277323.pdf
[41] Available at http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/RadiationDoseReduction/default.htm

activities by conducting risk-based domestic and foreign postmarket inspections, field exams, and sampling of medical device manufacturers to assess compliance with the Quality Systems regulations. These efforts include conducting inspections of reprocessors of single-use devices and manufacturers of radiation emitting products.

ORA's radiological health activities include methods development and analyses of radiation emitting products such as lasers, sunlamps and x-ray equipment to ensure that they comply with applicable performance standards. In addition to overseeing the regulated products on a surveillance or for-cause basis, ORA responds to emergencies and investigates incidents of product tampering and natural or intentional disasters that may affect FDA-regulated products.

ORA works with state contractors through the inspection contract program to support the mission of assuring the safety, quality, and effectiveness of medical devices. Inspections ensure that Class I (low risk) and Class II medical device manufactures are in compliance with the Quality Systems Inspection Technique (QSIT)/Good Manufacturing Practices (GMP) regulations.

ORA conducts import entry reviews, import field exams, import sample collections, and laboratory analyses to determine if import entries comply with the medical device registration and listing requirements and other general controls. These reviews assure that import entries declared as import for export are CDRH approved. ORA detains all import entries that do not comply with applicable regulations.

Public Health Outcome

In FY 2012, FDA conducted 453 inspections of foreign Medical Device and Radiological Health facilities in 35 countries. The dedicated foreign device cadre conducted approximately 166 of the inspections. In follow-up to objectionable conditions noted during these inspections, FDA issued 48 Warning Letters, 10 of which included placing the firm on Import alert with automatic detention. Specific examples of the dedicated device cadre accomplishments include:

- In April 2012, an ORA device cadre inspection revealed that a foreign manufacturer of cardiovascular devices failed to comply with cGMP requirements relating to the manufacture of blood pressure and ECG monitoring systems. As a result of the inspection, FDA issued a Warning Letter to the firm and these devices were placed on detention without physical examination, preventing them from entering the U.S. market.
- In May 2012, an ORA device cadre inspection of a foreign manufacturer of sterile syringes revealed several cGMP deficiencies. The firm was issued a Warning Letter and the devices were prevented from entering the U.S. Market.

During FY 2012, FDA classified and issued recall numbers for 57 Class I, 1,043 Class II, and 90 Class III recalls of medical device products. Also in FY 2012, ORA issued 127 notices identifying modifications to medical device-related Import Alerts encompassing numerous medical device products and medical device firms who were determined to be manufacturing or shipping violative medical device products. These actions were a result of ORA import surveillance collections and testing of regulated products at the time they were offered for import into the U.S., as well as for-cause sampling of imported products based on ORA findings of violations during inspections of foreign manufacturers. These notices serve to provide increased coverage at the border to assure these products are not available to the U.S. consumer.

In FY 2012, ORA's Office of Criminal Investigations (OCI) made 16 device related arrests and secured 18 device related conviction. Some representative cases include:

- In May 2012, a Criminal Information was filed, charging the defendant with introducing adulterated medical devices into interstate commerce in violation of the FD&C Act. According to the charges in the Information, the defendant acted with the intent to defraud and mislead the FDA with regard to the manufacturing procedures that were in place for an electro-surgical device used to cauterize tissue. This case characterizes the need for medical devices manufacturers to comply in accordance with GMPs as set forth in the FD&C Act.
- In July 2012, a defendant was sentenced for conspiring to introduce and deliver into interstate commerce an adulterated and misbranded device. The subject defendant and others endangered customers' lives by injecting them with commercial silicone, causing at least one victim to suffer lung damage from a substance not approved by the FDA. This investigation and other investigations involving adulterated and unapproved products are essential for preventing and protecting the public from dangerous products not approved for medical/cosmetic use by FDA.
- In August 2012, ORA worked to increase surveillance of contact lens shipments to ensure importations of these products met applicable requirements. Over 4,700 lines of contact lenses were imported during the increased surveillance period. ORA identified a number of firms for further follow up and continues to work to subject these non-compliant products to detention without physical examination. To ensure these efforts are maintained, OCI and Division of Import Operations (DIOP), in conjunction with other federal regulatory and investigative agencies, initiated Operation Double Vision. This operation intends to continue targeting the illegal importation, distribution and sales of counterfeit, misbranded or adulterated contact lenses, which are violations of the FD&C Act. These actions serve to keep these potentially debilitating devices out of the U.S. marketplace.

Additionally in FY 2012, ORA completed full national rollout of MARCS (Mission Accomplishment and Regulatory Compliance Services) Imports Entry Review (ER) and PREDICT (Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting)

to all 16 import Districts. MARCS Imports ER is FDA's new application used to make initial admissibility decisions, assign field work, and display the results of the PREDICT risk-based screening and database lookups. PREDICT is the FDA's electronic screening tool for import operations that replaces the legacy screening tool. PREDICT is designed to calculate a customized risk score for every line in an entry based on a number of factors including inherent risk of the product and the compliance history of the firms manufacturing or shipping the product. PREDICT also has automated database lookups to verify a firm's registration as well as a product listing and approval status. PREDICT will allow ORA to make more efficient and accurate admissibility decisions and allow ORA field office to target the examination of higher risk imported products.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
254202: Increase percentage of time CDRH meets the targeted deadline of 45 working days to review GMP information and issue Device Warning Letters. *(Output)*	FY 2012: 67% Target: 60% (Target Exceeded)	60%	60%	Maintain
254201: Number of domestic and foreign Class II and Class III device inspections. *(Output)*	FY 2012: 1,927 Target: 1,515 (Target Exceeded)	1,515	1,600	+85

Device Innovation and Regulatory Science – Center Activities
Base Amount: $50,818,428 (BA $45,497,761 / UF $5,320,667)

Public Health Focus

CDRH's Device Innovation and Regulatory Science investments focus on strengthening the U.S. research infrastructure by promoting high-quality regulatory science, facilitating the development and evaluation of transformative innovative technologies and scientific breakthroughs, and developing and sharing scientific information and tools to assess medical devices for American patients.

Public Health Outcome and Accomplishments

The United States is the global leader in medical device innovation. Each year, millions of American patients benefit from innovative medical devices that reduce suffering, treat previously untreatable conditions, extend lives, and improve public health.

CDRH's Device Innovation and Regulatory Science activities are essential to assure that advances in science and technology translate into improvements in human health. These activities include researching how new devices interact with the body, developing test methods for new technologies, testing products to identify root causes of failure, and developing epidemiological methods to help conduct postmarket studies of devices.

As a medical device is developed and evaluated, regulatory science plays an important role in evaluating its benefit-risk profile. It provides a vehicle through which CDRH collaborates with other stakeholders in developing tools that help manufacturers develop innovative products, and it helps manufacturers and FDA assess those products. The result is a more effective, efficient, and timely approach to national medical device development, assessment, and manufacturing.
For example, CDRH recently developed a virtual model family based on body scans of healthy volunteers. These computer-generated anatomically correct models, which include more than 80 types of tissue, are being used to investigate how medical devices interact with the body. Currently the models are being used to predict the best way to defibrillate children in the midst of a cardiac crisis, including the best placement of defibrillator leads and the right amount of electrical energy. CDRH plans to expand the virtual model family to allow developers to test early versions of their new devices on the virtual family models instead of on humans. This could reduce costs and speed the development of new products.
CDRH regulatory science activities also enhance the nation's ability to anticipate and respond to emerging public health challenges. For instance, increasing outbreaks of the ebola virus in humans highlight the need for the development of rapid and sensitive diagnostic tests for the potential bioterrorism agent. In response, CDRH developed and validated an assay, which it is currently modifying into a simple and rapid dip-stick test that can be used as a point-of-care test to improve the rapid detection and mitigation of this deadly virus.

After an approved device has moved into clinical use, CDRH regulatory science activities play an important role in developing novel methods to monitor and improve how devices are working and are used in real-world patient care. In one recent example, CDRH conducted studies of computed tomography (CT) breast imaging methods that compared the image quality and radiation dose of full and partial scans. CDRH found that the quality of the images was comparable between the two methods

and that CT dose can be reduced using the partial scan technique while maintaining image quality. This finding could lead to a substantial reduction in radiation exposure for U.S. patients and reduce operational cost for health care providers.

Through the Critical Path Initiative, CDRH continues to advance regulatory science and drive innovation and modernization of the product development and evaluation processes. Under Critical Path, CDRH recently developed a test method to assess the behavior of spinal total disc replacement devices under impingement conditions, which occurs when an implanted device reaches the limits of its range of motion. CDRH is now collaborating with external experts to develop a standard test method to assess impingement of these devices, helping industry and FDA better predict which new spinal disc devices will be clinically successful.

To leverage external expertise and resources and expand the nation's scientific capabilities, CDRH continues to develop collaborations with other government agencies, academia, industry, and professional societies. On December 3, 2012, the Medical Device Innovation Consortium (MDIC) was launched in partnership with the largest state-based life sciences trade association in the United States, Minnesota's LifeScience Alley. The MDIC is the first public-private partnership with the sole objective of advancing medical device regulatory science through the development and funding of regulatory science projects. The MDIC will augment CDRH's regulatory science expertise and help CDRH to keep pace with the increasing complexity of medical devices.

CDRH's regulatory science activities led to the receipt of the Diabetes Technology Society's 2012 Leadership Award. The award recognizes the tremendous contributions made by many CDRH staff who worked hard to improve the lives of patients with diabetes. It also recognizes the importance of regulatory science in bringing new technologies to patients. This was the first time an organization has received this award. It is also the first time the award recipient is from the field of regulatory science.

Device Innovation and Regulatory Science – Field Activities
Base Amount: $1,784,000 (BA: $1,784,000 / UF: $0)

Public Health Focus

ORA continues to make advancements in device safety for consumers by leveraging internal and external stakeholders, by conducting postmarket analytical methods development activities on pressing public health risks, and by developing a proactive FDA approach for post-market device testing. The focus of these activities is to:

- Develop new and improved methodology to support regulatory analysis
- Validate analytical methods to support enforcement activities
- Conduct product evaluation study projections to provide comprehensive postmarket surveillance information about devices.

In order to address rapidly expanding technologies in devices and other product areas, and to enhance current collaborative endeavors within and outside FDA, ORA continues to develop partnerships aimed to advance regulatory science. The focused efforts of ORA's laboratories, in collaboration with academia, federal and state partners, continue to ensure that suspect medical devices are removed from U.S. commerce.

Public Health Outcome

ORA's Winchester Engineering and Analytical Center (WEAC) conducts analyses and develops new analytical test methods for medical devices and radiation emitting electronic products in support of regulatory actions to ensure safe and effective medical devices.

ORA's medical device laboratory analyses utilize a risk-based approach focusing on device categories that have historically been responsible for a number of adverse events and recalls. The focused efforts of ORA's laboratories, in collaboration with academia, federal and state partners, continue to ensure that suspect medical devices are removed from U.S. commerce. ORA scientists' analyses also support OCI and US Attorneys' investigations and those of other partners.

ORA's laboratories also support the Devices Program through analysis and surveillance of samples for the Condoms and Gloves programs to assure these devices are safe and effective. These analyses help reduce the risk to the public and health care community of unnecessary exposure and transmission of blood-borne pathogens, particularly human immunodeficiency virus (HIV), hepatitis B, and hepatitis C infections by increasing the number of medical gloves analyzed at an expedited rate utilizing a high throughput model previously adopted for food borne outbreaks.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
252101: Number of technical analyses of postmarket device problems and performance. *(Output)*	FY 2012: 106 Target: 131 (Target Not Met)	131	125	-6
253207: Number of technical reviews of new applications and data supporting requests for premarket approvals. *(Output)*	FY 2012: 1,928 Target: 1,300 (Target Exceeded)	1,300	1,435	+135

Mammography Quality Standards Act (MQSA) – Center Activities
Base Amount: $11,978,012 (BA: $5,975,012 / UF: $6,003,000)

Public Health Focus

CDRH administers the Mammography Quality Standards Act (MQSA) by providing national quality standards for mammography services and helping mammography facilities meet these standards. The focus of the MQSA program is to assure high-quality mammography for early breast cancer detection, which can lead to a range of early treatment options and a decline in breast cancer morbidity and mortality in the United States.

Public Health Outcome

Twenty years ago, screening mammograms were – as they are today – a primary tool in reducing deaths from this disease. But different mammography facilities produced images of varying quality, which could make a reliable diagnosis difficult. MQSA was enacted to ensure that all of these facilities adhered to uniform standards, and therefore consistently produced breast images that could be optimally helpful in the diagnosis of breast cancer.

MQSA requires FDA-approved accreditation bodies to evaluate and accredit mammography facilities based on quality standards. A mammography facility is a hospital, outpatient department, physician's office, or other facility that conducts breast screening or diagnosis through mammography procedures. Once accredited, FDA or an FDA-approved state-certifying agency grants the facility a certificate, which allows it to legally operate. FDA, along with its state contract partners, annually inspects

approximately 8,500 certified mammography facilities in the United States. As a result of the MQSA program, 84 percent of the facilities are operating free of any violation, compared to 30 percent in CY 1995; and 99 percent of facilities had no serious violations of the law in CY 2012.

In FY 2012, the MQSA program inspected 100 percent of mammography facility inventories to help assure that all facilities meet baseline quality standards set by MQSA. CDRH works with facilities that are not in compliance to bring them into compliance. If these efforts fail, MQSA allows a variety of sanctions to be imposed, including certificate revocation and suspension.

Over the years, MQSA has motivated the strengthening and upgrading of mammography facilities' processes while manufacturers have continued to improve the performance of their mammography equipment, which today includes full-field digital mammography and three-dimensional mammograms. As a result, the 39 million American women who receive their annual mammograms can be confident that they are receiving the most up-to-date and reliable breast image. Thanks to early detection of the

disease and improved therapy, the U.S. mortality rate from breast cancer is about 17 percent – that's half the rate of breast cancer mortality world-wide – while the radiation dose used by American mammography facilities is one-tenth of what it was 40 years ago.

To give patients real-time information about adverse events occurring at mammography facilities, the corrective actions, and the operating status of facilities, the MQSA program now publishes the Mammography Facility Adverse Event and Action Report (MFAEAR) each time an adverse event at a mammography facility occurs. Previously the MQSA program published this report only once a year. In addition, mammography facilities, manufacturers, inspectors, and the general public can easily obtain up-to-date information on MQSA program regulations and guidance at FDA's webpage.[42]

Mammography Quality Standards Act (MQSA) – Field Activities
Base Amount: $15,820,000 (BA: $2,743,000 / UF: $13,077,000)

Public Health Focus

To protect consumers and advance public health for women, ORA continues to focus resources on health prevention by carrying out the mammography facility inspection contract program with the states, which includes an annual audit of state inspectors and FDA-provided training for state inspectors.

Public Health Outcome

The ORA Field force supports the MQSA program by managing state-conducted inspections annually and by conducting foreign inspections to ensure the safety of mammography conducted in military facilities located in foreign countries.
The Field:

- Inspects certified mammography facilities
- Conducts follow-up inspections to determine compliance with terms of corrective action plans based on non-compliances found during prior inspections
- Performs on-site quality assurance audits of FDA and State MQSA inspectors to ensure their proficiency in conducting mammography facility inspections.

To ensure high quality facility inspections conducted by the states, ORA coordinated with CDRH to offer annual MQSA training courses to new state inspectors as well as to provide continuing education for certified state inspectors. In addition to annual MQSA training, FDA also added free online training in FY12 to ensure FDA and State MQSA inspectors are able to maintain their required continue education units if training funds are limited.

[42] Available at http://www.fda.gov/radiation-emittingproducts/mammographyqualitystandardsactandprogram/default.htm

ORA works with the states to maintain MQSA contract program quality standards, which ensure that women receive high quality mammography for early breast cancer detection. Maintaining the contract program through collaboration with qualified state partners maximizes resources dedicated to MQSA and ensures that a greater number of mammography facilities are inspected each year than could be accomplished by an individual program alone.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
254101: Percentage of an estimated 8,700 domestic mammography facilities that meet inspection standards, with less than 3% with Level I (serious) problems. *(Outcome)*	FY 2012: 99.3% Target: 97% (Target Exceeded)	97%	97%	Maintain

Information Technology Investments – Devices and Radiological Health Program Activities (Base Amount displayed as a non-add item: $61,466,193)

CDRH-specific IT planning and development efforts support the Center's strategic priorities. CDRH adheres to the concept of managing the total product life cycle of medical devices and radiation-emitting products, including premarket evaluation and review, oversight of production practices, and tracking and evaluation of products in the marketplace. The IT systems tailored for CDRH enhance or expand the total product life cycle and continue the movement away from a paper environment to an electronic environment. CDRH builds public-facing systems that help the public and regulated industry to address information requirements and interact with the agency, and internal systems that provide the data and information necessary for CDRH to perform its mission efficiently.

CDRH depends heavily on modernized IT, informatics standards, and the continued migration from paper to standardized electronic submissions and communications. CDRH also leverages commercial off-the-shelf (COTS) software and services, government off-the-shelf software (GOTS) and FDA technologies and initiatives whenever possible. Specifically, CDRH upgraded its tracking and reporting systems to meet the new goals and commitments of the new MDUFA legislation, including the utilization of COTS software for a new CDRH Document Manager (DocMan). Examples for FY 2014 are the Unique Device Identification (UDI) database, new capabilities for storing and searching for data to support the premarket review processes, and the CDRH Entry (CEntry) premarket legacy database modernization.

Public Health Focus

Investments in CDRH's information technology programs are paramount for supporting its mission of protecting and promoting public health. CDRH is able to strengthen its premarket review program by better tracking and reporting on premarket submissions, which contributes to more predictable, consistent, transparent, and efficient reviews. It continues to improve its data analytics and mining capabilities for postmarket surveillance and compliance-based actions to help better identify poorly performing devices more quickly and accurately. It is working on ways to provide more suitable public access to understandable science-based information, which will allow consumers, patients, their caregivers, and providers to make health care decisions. Furthermore, the Center recognizes that a tremendous amount of knowledge is created by employees and that a modernized knowledge management technical infrastructure is necessary to facilitate the search, retrieval, and dissemination of knowledge across organizational boundaries.

Funding History Table with FTE Totals

The following table displays funding and Full Time Equivalent (FTE) staffing levels from FY 2010 through FY 2013, plus FY 2014 request.

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
FY 2010 Actual	$369,971,000	$313,452,000	$56,519,000	1,801
FY 2011 Actual	$378,509,000	$322,182,000	$56,327,000	1,902
FY 2012 Actual	$390,954,000	$322,636,000	$68,318,000	1,986
FY 2013 CR	$378,174,000	$324,647,000	$53,527,000	2,013
FY 2014	$435,046,000	$320,544,000	$114,502,000	2,026

Summary of the Budget Request

The FY 2014 budget request for the Devices and Radiological Health Program is $435,046,000. This amount is an increase of $59,057,000 above the FY 2012 Enacted Level. The Center for Devices and Radiological Health amount in this request is $332,247,000, supporting 1,503 FTE. The Field amount is $102,799,000, supporting 523 FTE.

The base funding for the Devices and Radiological Health Program is $375,989,000, which includes $280,655,000 for the Center for Devices and Radiological Health activities and $95,334,000 for the Devices and Radiological Health Field activities.

Base funding allows the Devices and Radiological Health Program to meet its mission to protect and promote public health. By focusing on high priority areas, the Devices Program will continue to assure that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. Consumers, patients, their caregivers, and providers will have understandable and accessible science-based information about the products we oversee. Finally, the Devices Program will facilitate medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and assuring consumer confidence in devices marketed in the United States.

The initiative proposed under the FY 2014 budget request supports HHS, FDA and Presidential public health priorities to advance medical countermeasures. This investment fosters the rapid and reliable development of medical countermeasures to respond to public health threats and ensure that Americans have access to the medical devices needed to counter a deliberate chemical, biological, radiological or nuclear (CBRN) attack or a naturally occurring epidemic.

Budget Request Details

Pay Increase (Total Program: +$1,417,000)

The request for $320,544,000 in total BA for the Devices and Radiological Health Program reflects a pay increase for Civilian and Commissioned Corps staff. The Center's portion of the increase is $1,060,000 and the Field's portion is $357,000.

Adjustment to Base (Total Program: -$4,268,000 and -29 FTE)

The budget request for $320,544,000 in total budget authority for the Devices and Radiological Health Program also reflects a reduction to the base of -$4,268,000 for FY 2014. The Center's portion of this reduction is -$3,194,000 and -23 FTE; the Field's portion of this reduction is -$1,074,000 and -6 FTE.

Premarket Device Review

Center Activities –
FY 2012 Enacted Base: $143,183,421 (BA: $119,291,291 / UF: $23,892,130)
FY 2014 Total Increase above Base: (+$38,651,652 / 31 FTE)
FY 2014 Increase above Base for Current Law User Fees (MDUFA): (+$38,169,652 / 31 FTE)

FY 2014 Initiative Increase:

Medical Countermeasures (MCM): +$482,000 (2 FTE non-add)

Enhance the Review and Approval Processes for MCMs: CDRH will foster the development and deployment of MCMs by strengthening its program of technical assistance – including the development of regulatory management plans – for the developers of the highest-priority MCMs. FDA will also ready MCMs for use under an EUA in advance of an emergency.

Modernize the Legal, Regulatory and Policy Framework for Effective Public Health Response: CDRH will continue to work collaboratively with HHS to examine the legal framework and the regulatory and policy approaches for MCM development and availability to ensure these adequately support emergency preparedness and response. These efforts include strengthening FDA's program to support rapid deployment and pre-event planning and positioning of MCMs.

Field Activities –
FY2012 Enacted Base: $8,465,000 (BA: $7,457,000 / UF: $1,008,000)
FY 2014 Total Increase above Base: (+$811,000 / 0 FTE)
FY 2014 Increase above Base for Current Law User Fees (MDUFA): (+$811,000 / 0 FTE)

Postmarket Safety

Center Activities –
FY 2012 Enacted Base: $39,115,099 (BA: $35,150,896 / UF: $3,964,204)
FY 2014 Total Increase above Base: (+$6,333,143 / 0 FTE)
FY 2014 Increase above Base for Current Law User Fees (MDUFA): (+$6,333,143 / 0 FTE)

Field Activities –
FY 2012 Enacted Base: $791,000 (BA: $739,000/ UF: $52,000)
FY 2014 Total Increase above Base: (+$42,000 / -3 FTE)
FY 2014 Increase above Base for Current Law User Fees (MDUFA): (+$42,000 / -3 FTE)

Compliance, Enforcement, and Radiation Safety

Center Activities –
FY 2012 Enacted Base: $35,560,040 (BA: $35,560,040 / UF: $0)
FY 2014 Total Increase above Base: ($0 / 0 FTE)

Field Activities –
FY2012 Enacted Base: $68,474,000 (BA: $68,474,000 / UF: $0)

FY 2014 Total Increase above Base: (+$7,329,000 / 39 FTE)
FY 2014 Increase above Base for Proposed User Fees (Medical Product Reinspection): (+$3,651,000 / 24 FTE)
FY 2014 Increase above Base for Proposed User Fees (International Courier): (+$3,678,000 / 15 FTE)

Device Innovation and Regulatory Science

Center Activities –
FY 2012 Enacted Base: $50,818,428 (BA $45,497,761 / UF $5,320,667)
FY 2014 Total Increase above Base: (+$8,741,205 / 0 FTE)
FY 2014 Increase above Base for Current Law User Fees (MDUFA): (+$8,500,205 / 0 FTE)

FY 2014 Initiative Increase:

Medical Countermeasures (MCM): +$241,000 (1 FTE non-add)

Advance Regulatory Science for MCM Development and Evaluation: CDRH will sustain its MCM regulatory science program, relying heavily on partnerships with industry, academia and U.S. government partners that enable FDA to harness cutting-edge science and apply innovative approaches to the regulatory process to improve MCM development timelines and success rates. In particular, FDA will focus investments in regulatory science on

- Developing and qualifying tools to assess efficacy, such as animal and biomimetic models
- Developing methods to assess product quality and assays to support the release of MCMs
- Developing and assessing advanced diagnostic tests
- Developing novel manufacturing platforms.

Field Activities –
FY2012 Enacted Base: $1,784,000 (BA: $1,784,000 / UF: $0)
FY 2014 Total Increase above Base: (+$0 / 0 FTE)

Mammography Quality Standards Act (MQSA)

Center Activities –
FY 2012 Enacted Base: $11,978,012 (BA: $5,975,012 / UF: $6,003,000)
FY 2014 Total Increase above Base: (+$0 / 0 FTE)

Field Activities –
FY 2012 Enacted Base: $15,820,000 (BA: $2,743,000 / UF: $13,077,000)
FY 2012 Total Increase above Base: (+$0 / 0 FTE)

CDRH Program Activity Data (PAD) for FY 2014 CJ			
CDRH Workload and Outputs	FY 2012 Actual	FY 2013 Estimate [14/]	FY 2014 Request
Original PMAs and Panel-Track Supplements (without Advisory Committee input)			
Workload [1/]	30	30	30
Total Decisions [2/]	53	45	40
Approved [3/]	22	25	25
Original PMAs and Panel-Track Supplements (with Advisory Committee input)			
Workload	3	3	3
Total Decisions [2/]	7	6	6
Approved	4	4	4
Modular PMAs			
Workload	63	65	65
Actions [4/]	58	60	60
180-day PMA Supplements			
Workload	210	220	220
Total Decisions [5/]	124	125	125
Approved	102	100	100
Real Time PMA Supplements			
Workload	305	300	300
Total Decisions [6/]	295	300	300
Approved	269	270	270
510(k) Premarket Notifications			
Workload	3,994	4,000	4,000
Total Decisions [7/] *(SE & NSE)*	3,335	3,300	3,300
Cleared [9/] *(SE)*	3,173	3,100	3,100
Humanitarian Device Exemptions (HDE)			
Workload	5	6	6
Total Decisions [2/]	5	5	5
Approved	3	3	3
Investigational Device Exemptions (IDE)			
Workload	260	260	260
Total Decisions [8/]	258	260	260
Approved	207	205	205
Investigational Device Exemption Supplements			
Workload	3,605	3,900	3,900
Closures [10/]	3,610	3,800	3,800
Pre-Submissions			
Workload	1,075	2,250	2,500
Closures [11/]	1,099	2,200	2,400
Standards			
Total Standards Recognized for Application Review	1,000	1,050	1,100
Medical Device Reports (MDRs) [12/]			
Reports Received	937,676	1,398,781	1,818,415
Analysis Consults [13/]	763	675	675

Footnotes:

[1/] 'Workload' includes applications received and filed. (Receipt Cohort)

[2/] 'Total Decisions' include approval, approvable, approvable pending GMP inspection, not approvable, withdrawal, and denial - regardless of the fiscal year received. (Decision Cohort)

[3/] 'Approved' includes applications approved regardless of the fiscal year received. (Decision Cohort)

[4/] 'Actions' include accepting the module, request for additional information, receipt of the PMA, and withdrawal of the module. (Decision Cohort)

[5/] 'Total Decisions' include approval, approvable, approvable pending GMP inspection, and not approvable. (Decision

[6/] 'Total Decisions' include approval, approvable, and not approvable. (Decision Cohort)

[7/] 'Total Decisions' include substantially equivalent (SE) or not substantially equivalent (NSE). (Decision Cohort)

[8/] 'Total Decisions' include approval, approval with conditions, disapproved, acknowledge, incomplete, withdrawal, or other. (Decision Cohort)

[9/] 'Cleared' includes substantially equivalent decisions (SE). (Decision Cohort)

[10/] 'Closures' include approval, approval with conditions, disapproved, acknowledge, incomplete, no response necessary, withdrawal, or other. (Decision Cohort)

[11/] 'Closures' include a meeting with Industry, deficiency, or other. (Decision Cohort)

[12/] 'MDRs' include individual and summary Medical Device Reports.

[13/] 'Analysis Consults' include analysis of individual and summary Medical Device Reports (analyzing trends and signals in MDR data).

[14/] Spending authority has been adjusted pursuant to PL 112-175, Section 101(c) for the applicable user fee programs.

Combined Field Activities – ORA
Program Activity Data

Field Devices Program Activity Data (PAD)

Field Devices Program Workload and Outputs	FY 2012 Actuals		FY 2013 [1] Estimate		FY 2014 Request
FDA WORK					
DOMESTIC INSPECTIONS					
UNIQUE COUNT OF FDA DOMESTIC DEVICES ESTABLISHMENT INSPECTIONS	***2,741***		***2,864***		***2,864***
Bioresearch Monitoring Program Inspections	295		300		300
Pre-Market Inspections	54		67		67
Post-Market Audit Inspections	44		34		34
GMP Inspections	1,790		1,592	[2]	1,592
Inspections (MQSA) FDA Domestic (non-VHA)	521		723		723
Inspections (MQSA) FDA Domestic (VHA)	43		43		43
Domestic Radiological Health Inspections	90		205		205
Domestic Field Exams/Tests	215		215		215
Domestic Laboratory Samples Analyzed	183		183		183
FOREIGN INSPECTIONS					
UNIQUE COUNT OF FDA FOREIGN DEVICES ESTABLISHMENT INSPECTIONS	***453***	[2]	***603***		***603***
Foreign Bioresearch Monitoring Inspections	10		25		25
Foreign Pre-Market Inspections	27		31		31
Foreign Post-Market Audit Inspections	31		19		19
Foreign GMP Inspections	386		519	[3]	519
Foreign MQSA Inspections	14		15		15
Foreign Radiological Health Inspections	23		45		45
TOTAL UNIQUE COUNT OF FDA DEVICE ESTABLISHMENT INSPECTIONS	***3,194***		***3,467***		***3,467***
IMPORTS					
Import Field Exams/Tests	18,821		18,821		18,821
Import Laboratory Samples Analyzed	1,123		1,123		1,123
Import Physical Exam Subtotal	**19,944**		**19,944**		**19,944**
Import Line Decisions	13,651,985		19,445,808		27,698,496
Percent of Import Lines Physically Examined	0.15%		0.10%		0.07%
STATE WORK					
UNIQUE COUNT OF STATE CONTRACT DEVICES ESTABLISHMENT INSPECTIONS	***7,918***		***7,929***		***7,929***
UNIQUE COUNT OF STATE PARTNERSHIPS DEVICE ESTABLISHMENT INSPECTIONS	**59**		**59**		**59**
Inspections (MQSA) by State Contract	6,792		6,800		6,800
Inspections (MQSA) by State non-Contract	1,107		1,110		1,110
GMP Inspections by State Contract	19		19		19
State Partnership GMP Inspections	59		59		59
State Contract Devices Funding	81,685		85,000		85,000
State Contract Mammography Funding	8,692,710		9,127,350		9,127,350
Total State Funding	**$8,774,395**		**$9,212,350**		**$9,212,350**
GRAND TOTAL DEVICES ESTABLISHMENT INSPECTIONS	***11,171***		***11,455***		***11,455***

[1] Spending authority has been adjusted pursuant to PL 112-175, Section 101(c) for the applicable user fee programs.

[2] The FY 2012 actual unique count of foreign inspections includes 11 OIP inspections (10 for China and 1 for India).

[3] The FY 2013 planned mix of domestic versus foreign GMP inspections shifts quite a few more inspections into the foreign arena, with a corresponding decrease to domestic GMP inspections in comparison to the FY 2012 actuals, but the overall coverage is not changing. This is being done to achieve greater parity of the foreign versus domestic inspections and thus level out the inspection cov

National Center for Toxicological Research Program

The following table displays funding and full time equivalent (FTE) staffing levels for FY 2012 through FY 2014.

FDA Program Resources Table[42]
(Dollars in thousands)

	FY 2012 Enacted	FY 2012 Actual	FY 2013 CR	FY 2014 Request	FY 2014 +/- FY 2012
Program Level	**$60,039**	**$60,023**	**$60,406**	**$59,494**	**$(545)**
Center	$60,039	$60,023	$60,406	$59,494	$(545)
FTE	272	269	272	272	3
Program Level FTE	**272**	**269**	**273**	**272**	**3**
Budget Authority	**$60,039**	**$60,023**	**$60,406**	**$59,494**	**$(545)**
Center	$60,039	$60,023	$60,406	$59,494	$(545)
Budget Authority FTE	**272**	**269**	**273**	**272**	3

FDA's National Center for Toxicological Research (NCTR) operates under the following legal authorities:

Federal Food, Drug, and Cosmetic Act [21 U.S.C. 393(b) (1)]
Food and Drug Administration Modernization Act [43]
Food and Drug Administration Amendments Act of 2007 [1]
FDA Food Safety Modernization Act (P.L. 111-353)

Allocation Method: Direct Federal/Intramural

Program Description and Accomplishments

NCTR was established in 1971 as a national scientific resource to conduct peer-reviewed research that translates knowledge and technology into processes that improve FDA's ability to assess the safety of regulated products. NCTR supports HHS and FDA strategic priorities by advancing regulatory science and innovation with new scientific tools, technologies, methods, early predictors of toxicity risk, and research data. NCTR provides colleagues with technical advice and training and leads national and international collaborations that enhance FDA's basis for sound, science-based regulatory decisions worldwide and that improve global public health.

[42] Spending authority has been adjusted pursuant to PL 112-175, Section 101(c) for the applicable user fee programs.

[43] Authorities under this act do not appear in sequence in the U.S. Code. The authorities are codified as amended in scattered sections of 21 U.S.C.

FDA risk decisions and guidance documents use NCTR's research data to improve patients' safety and quality of life and to generate health-care savings. NCTR research is focused on two subprograms:

- Evaluating Toxicity of FDA-Regulated Products
- Modernizing Toxicology to Support the FDA Mission.

Evaluating Toxicity of FDA-Regulated Products – Center Activities
Base Amount: $22,076,102 (All BA)

Public Health Focus
This subprogram focuses on developing innovative scientific tools and methods to better protect public health by *preventing* problems rather than *reacting* to problems after they occur. NCTR identifies early predictors of toxicity for FDA-regulated products by:

- Defining and characterizing individual responses to FDA-regulated products
- Identifying health hazards to help FDA establish science-based standards
- Defending the food system against bioterrorism as part of the FDA Food Safety Modernization Act (FSMA) and key priorities of the President's Food Safety Working Group.

Public Health Outcomes
With budget-authority resources NCTR conducts vital, cutting-edge research to advance the safety of FDA-regulated products. NCTR research will:

- Identify product issues sooner, so FDA can act faster to protect public health
- Lower costs for industry, health care, and the consumer because adverse effects can be identified earlier in product development
- Provide new understanding of a contaminant's toxicity and the relationship to levels of exposure so FDA can issue improved guidelines for use
- Identify an individual's response to a food, drug, nutrient, or environmental chemical, resulting in improved personal health
- Support FSMA by providing strategies to reduce pathogens in the food supply.

Safety Evaluation of Antimicrobial Residues in Food — NCTR conducts research that addresses questions raised by national regulatory authorities and scientific advisory groups, such as questions pertaining to FDA Guidance to Industry #152, which was recently accepted as an international guideline (VICH Guideline 36). The questions from the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) were about the potential impact of drug residues in foods derived from animals treated with antimicrobial agents on the human intestinal microbiota. In 2012, NCTR scientists used microbiological and analytical chemistry methods to show that low levels of enrofloxacin, a veterinary antimicrobial, had no adverse effects and did not disrupt intestinal microbial communities in human fecal slurries.

Both NCTR's scientific advice in the development of the guidelines and NCTR research, have improved the safety evaluation and risk assessment of the impact of antimicrobial residues helping to ensure food safety.

Triclosan Effects on Fat-Cell Maturation — NCTR scientists collaborated with CBER and the Arkansas Department of Health in 2012 to conduct a study on triclosan, a common antimicrobial agent. Triclosan is known to be toxic to tissue at high doses; but the toxicity of triclosan at very low, continuous exposures from hygiene products requires further study. Results were published in *Toxicology and Applied Pharmacology*.

Evaluation of Acetaminophen-Induced Liver Toxicity — Acetaminophen is a widely used over-the-counter drug capable of causing severe, and sometimes fatal, liver injury. To improve the detection of such agents in nonclinical testing and its diagnosis in humans, NCTR identifies better biomarkers of liver toxicity to improve the understanding and mechanisms of toxicity.
In 2012, NCTR scientists used cutting-edge technologies to learn about the biological response leading to acetaminophen's toxicity and discovered new biomarkers in rats that may be better than those used today. Future research will study other chemicals damaging to the liver to support these biomarkers as universal indicators of liver injury or to find new and better biomarkers.
Evaluation of Potential Toxicity for Bisphenol A (BPA) — Due to its widespread use in consumer products and in medical devices, people are exposed to trace levels of BPA daily. According to the 2003-2004 National Health and Nutrition Examination Survey, 93% of urine samples from people ages six and older had detectable levels of a BPA metabolite. This survey raised health concerns about BPA exposure, particularly in the fetus resulting from the mother's exposure, and in newborns exposed directly to BPA.

- Providing FDA more scientific data for these special populations, NCTR researchers completed a study of BPA in rats using a broad range of oral doses to pregnant dams and the pups after birth. NCTR evaluated reproductive development and a broad range of physiological endpoints to assess possible adversity induced by BPA in humans or animals. The findings resulted in seven manuscripts published in four scientific journals.
- NCTR will use funding to continue to develop pharmacokinetic data on BPA in fetal, neonatal, and adult rodent and non-human primate models. Scientists will combine data from these animal models with human data from a collaborative clinical study with the National Toxicology Program for predictive modeling of tissue exposures to BPA from food-contact materials, medical devices, and other environmental sources. To date, findings from the clinical study have resulted in 10 publications in peer-reviewed journals.

- NCTR also is conducting long-term studies to determine possible toxic effects in rats exposed to a wide range of BPA doses through adulthood. The goal is to provide FDA with a scientific foundation for regulatory risk-assessment.

Neurological Effects of Pediatric Anesthetics — Each year in the United States alone, more than one million children, four years of age or less, undergo surgical procedures requiring anesthesia.[44] NCTR scientists are evaluating the neurological effects of pediatric anesthetic use in developing nonhuman primates, an animal model closely related to humans. Based on NCTR findings that a single 24-hour episode of general anesthesia induced by ketamine during the first week of life causes long-lasting deficits in the cognitive abilities of nonhuman primates, along with other researchers' findings, CDER convened an advisory committee meeting to review studies on the use of anesthesia in the pediatric setting. NCTR scientists continue work with CDER reviewers to assist in developing guidelines to assess developmental neurotoxicity. The data is vitally important for FDA's regulatory needs and to identify compounds to prevent or reduce anesthetic-induced neurotoxicity.

Foodborne Pathogens — NCTR's research to identify food-related health hazards and defend the food system is designed to decrease the frequency and severity of food- and feed-borne illness outbreaks, thus diminishing the burden on the U.S. economy.

- NCTR supports FSMA by conducting research to establish risk-based strategies to set antimicrobial drug-residue limits in animal products. In FY 2012, NCTR scientists developed a technique to simultaneously detect the presence of 131 antimicrobial resistance genes that confer resistance to 22 different antibiotics used either in human clinical or veterinary practice. This method is more cost-effective and provides more information than is currently available.
- NCTR collaborated with CFSAN and the Illinois Institute of Technology to determine the most effective agent for inactivating ricin, a potential biological warfare agent targeting the food supply. In 2012, scientists found that sodium hypochlorite (ingredient in household bleach) and hypochlorite-containing products are the most effective agent to inactivate ricin in dried food residues — such as infant formula, peanut butter, pancake mix — on stainless steel surfaces.
- NCTR, in collaboration with ORA, developed a detection method for *Salmonella* that indicates antibiotic resistance. The current official FDA cell-culturing methods are time-consuming and labor-intensive, resulting in slower pathogen detection by regulatory laboratories. This new method rapidly detects *Salmonella* and enables simultaneous detection of antibiotic-resistance markers in food samples. The method is currently being validated. In April 2012, NCTR hosted a Food Safety Conference at the NCTR campus with attendees from government, academia, and industry. NCTR antimicrobial-resistance studies were highlighted.

[44] Rabbitts J, Groenewald CB, Moriarty JP, Flick R. Epidemiology of Ambulatory Anesthesia for Children in the United States: 2006 and 1996. Anesth Analg 2010; 111: 1101-15.

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
263103: Conduct translational and regulatory research to advance the safety of products that FDA regulates. *(Output)*	FY 2012: 1) Consortium formed that includes members from industry, academia, and other government agencies that will provide consideration and deliberation on imaging issues and endpoints. (Target Met) 2) Published and presented findings related to exposure, endpoint, and prevention approaches to improve the safe use of anesthetics in children. (Target Met)	1) Establish an imaging consortium of scientific experts from NCTR, CDER, and from other government agencies, industry, and academia to refine the imaging tools 2) Determine pathways of toxicity and preventive strategies for pediatric anesthetics using a high-speed, high-volume method (zebrafish)	1) Complete a project aimed at identifying biomarkers (biological indicators) to predict the effects of cancer drugs on the heart. 2) Complete a simulation protocol to help reduce the uncertainty in the risk-assessment of BPA 3) Evaluate the effects of methylphenidate, a drug for the treatment of Attention-Deficit Hyperactivity Disorder, using bioimaging techniques	N/A

Modernizing Toxicology To Support the FDA Mission
Base Amount: $37,962,898 (All BA)

Public Health Focus
NCTR research will result in new technologies and standards that provide enhanced risk assessment for reviewers and strengthen public-health assurance for new and existing products by:

- Identifying and developing innovative tools and using new technologies to evaluate the toxicity of FDA-regulated products
- Developing, validating, and providing guidance to FDA on new technologies
- Developing new rapid-detection methods for regulated-compound contaminants
- Dharacterizing biomarkers allowing FDA to identify science-based individualized therapies that increase treatment effectiveness and reduce adverse events
- Ddvancing the use of regulatory science principles though global meetings, scientific exchange and training to address safety demands of the global marketplace.

Public Health Outcomes

Under this subprogram, NCTR will research new technologies and approaches to assess risk and ensure the safety of FDA-regulated products, leading to:

- Improved personalized medicine, saving the American public the cost of unsafe and ineffective medical products and therapies
- Biomarkers of risk that improve the time and expense of product development
- Expanded imaging capabilities, reducing the need for costly and dangerous surgical procedures and preventing recurring illness
- Innovative tools and science to better evaluate FDA-regulated products
- Enhanced understanding of nanomaterials
- Improved and faster contamination-source identification in the food-supply chain.

Contemporary advances are clearly seen today in health care thanks to research. NCTR accomplishments provide FDA with innovative technologies and methods to assess the safety of regulated products. With a worldwide outstanding scientific reputation, NCTR also enhances FDA globalization efforts in regulatory science.

Regulatory Science Outreach and Globalization

- Global Summit on Regulatory Science (GSRS) — In 2011, NCTR hosted the first annual GSRS. The global event was very successful laying the foundation for annual meetings. The second annual GSRS was held in May 2012 in China. The conferences provide a platform where international regulators, policy makers, and scientists can exchange views on how to develop, apply, and implement innovative methodologies into regulatory assessments. To engage the global community and harmonize strategy via global collaboration, the GSRS will be held in different locations on an annual basis. The next GSRS is scheduled for Sep 2013. For more information visit http://www.fda.gov/AboutFDA/CentersOffices/OC/OfficeofScientificandMedicalPrograms/NCTR/WhatWeDo/ucm289679.htm.
- Global Coalition for Regulatory Science Research — The GSRS has prompted the development of a Global Coalition for Regulatory Science Research (GCRSR) with scientific experts from around the world. NCTR is leading the establishment of the new coalition. This GCRSR will engage the research communities to integrate emerging technologies into regulatory research and build the global scientific infrastructure needed to advance and promote regulatory science.

Certificate in Regulatory Science — NCTR and the University of Arkansas for Medical Sciences (UAMS) developed a Regulatory Science Graduate Certificate program that started in Fall 2012, and plan to offer a Masters program in 2014. NCTR researchers serve as adjunct professors and provide a contextual learning opportunity for students who will be available to fill jobs in the emerging drug-development and biotechnology sectors of government and industry. This is a direct result of the 2011 FDA/NCTR

memorandum of understanding (MOU) with the State of Arkansas to advance regulatory science. For more information visit: http://publichealth.uams.edu/academics/certificates/certificate-in-regulatory-science.

Nanotechnology

The science involving manipulation of materials on the nano scale is an emerging technology and has the potential to be used in a broad array of FDA-regulated products. The NCTR/ORA Nanotechnology Core Facility provides FDA with a state-of-the-art science program that will provide research data to aid the development of guidelines for the safe and effective use of these materials in drug products, devices, foods, cosmetics, and dietary components. NCTR aims to better understand the safety and efficacy of products through investments in three areas, including: 1) education and training of regulatory scientists, 2) enhanced equipment and core facilities, and 3) targeted research activities. FDA's research generates data to assess the safety and responsible development of products using nanomaterials.

In FY 2012, the Core Facility established quantitative methods for titanium, iron, zinc, chromium, and cobalt, as well as, developed and validated methods to support research in the area of quantum particle size and the presence of ions to support NCTR and FDA research.

Also in FY 2012, the Core Facility staff provided hands-on instrumentation training for scientists from each FDA Center and also UAMS researchers.

NCTR is collaborating with five Arkansas research universities to conduct studies that will synthesize the carbon-based nanomaterials similar to those anticipated to be found in FDA-regulated products. The partners will develop sensitive methods for quantifying nanomaterials and provide quantitative information for FDA to use in regulatory decision making.

In addition to providing education, NCTR is conducting studies to determine if nanomaterials cross the blood-brain barrier in rodents and if they can damage brain tissue. The data to date shows some of these materials do interact with blood-brain-barrier cells and generate an adverse reaction. This data provides a better understanding of nanomaterials used in many FDA-regulated products.

Nanoscale materials, such as zinc oxide and titanium oxide, are often found in sunscreen and cosmetics. NCTR is evaluating the effect of sunscreen and cosmetics on models representative of human skin to determine if nanomaterials penetrate the skin and encourage bacterial growth. This research will provide the data to determine the potential health effects of skin exposure to nanomaterials.

NCTR is conducting studies to increase information on the digestive absorption of nanomaterials and assess its safety. Exposure to nanoparticles — nanosilver especially, because of its antimicrobial use — from food or food packaging is the greatest nano-related risk to consumers. The research is studying nanosilver ingested by rodents to

determine the magnitude of risk, and developing methods to measure nanosilver migration, providing data for regulatory decisions.

Liver Toxicity

As the second leading cause of acute liver failure and the most likely reason a drug is withdrawn from the market, liver toxicity is an important focus of NCTR research.

To address this public-health issue, a Liver Toxicity Knowledge Base (LTKB) was developed at NCTR. The LTKB improves drug safety, aids in the understanding of liver toxicity, and enables the development of predictive tools to identify liver-toxicity during drug development. The LTKB will also reduce the expense of withdrawing drugs after they are on the market, and will protect patients from liver injury. NCTR will continue to expand the knowledge base through 2014. To access the alpha version of LTKB visit: http://www.fda.gov/ScienceResearch/BioinformaticsTools/LiverToxicityKnowledgeBase/default.htm.

In FY 2012, NCTR scientists developed three predictive computer models that exhibit a high positive predictive value for drugs that cause severe liver injury. One of the models, called Drug-Induced Liver Injury Predictive System which combines individual models that predict 13 types of liver injury into one system, was published in *PLoS Computational Biology*. Manuscripts for the other two predictive models will be published this year. NCTR will continue exploring the potential of predictive computer models to screen new drug candidates for liver toxicity; and possibly kidney and heart toxicity.

Personalized Medicine

Advances in personalized medicine can identify patients most likely to benefit from or experience adverse reactions to particular drugs. Investment in this research will reduce the cost and failed expectations associated with unsafe and ineffective medical products and therapies for individual patients.

Identifying Sensitive Subpopulations to Drug-Induced Liver Toxicity — The post-market discovery of unanticipated drug-induced liver toxicity may result from the existence of a small number of sensitive patients who are not detected during pre-clinical and clinical testing. However, when the drug is marketed to large numbers of people in the overall population, the liver toxicity starts to appear.

NCTR scientists developed statistical models and data-mining algorithms using a computerized system to characterize sensitive subpopulations and evaluate the potential side effects of drugs with data from the FDA Adverse Event Reporting System. NCTR's initial analysis resulted in a 2012 publication in the *Journal of Biopharmaceutical Statistics* and subsequent publications will follow. With this information, FDA can offer patients and their health providers valuable information to guide their decision whether to use a particular drug. Instead of withdrawing such a drug, the FDA can require the manufacturer to include appropriate warnings and to specify patient-marker criteria for

prescribing it. NCTR continues to develop statistical methods and data mining algorithms to advance medical product safety.

Noninvasive Bio-Imaging Research

NCTR's bio-imaging facility provides advanced infrastructure for research to develop noninvasive, magnetic resonance (MR) imaging biomarkers of disease progression and drug efficacy. NCTR's imaging tools allow FDA to gather detailed information not previously obtainable and may lead to the development of new biomarkers for conditions such as microvascular disorders — a leading cause of mortality and disability in stroke victims. Currently the diagnosis of certain neurological disorders is only available using invasive methods with a high cost and level of risk for the patient. The noninvasive biomarkers being developed offer the possibility of better diagnosis with less risk and cost to the patient.

NCTR also is developing novel methods of validating MR imaging scans. Once verified, these methods may provide a way to distinguish between an adverse event, such as a tumor, and a normal event, such as scar tissue, without invasive surgery. NCTR is gathering data for computer models to help distinguish tissue status. Going forward, NCTR scientists will use MR spectroscopy (MRS) to noninvasively investigate the neurochemical makeup of laboratory animals' brains. MRS approaches are being used to assess the involvement of key neurotransmitters during brain development and to understand the expression of neurotoxicity. For more information visit: http://www.fda.gov/AboutFDA/CentersOffices/OC/OfficeofScientificandMedicalPrograms/NCTR/WhatWeDo/NCTRResearchPriorities/ucm085599.htm.

Biomarker Development

For FDA to continue the important mission of protecting public health, biomarkers of health and disease status must continue to be developed.

Early Detection of Liver Toxicity — Funding for NCTR scientists allow continued research to identify biomarkers, including a large project to identify more sensitive and specific biomarkers of chemical-driven liver damage. This project uses omics technologies and preclinical animal models to identify compounds not typically identified as being toxic to the liver. A finding from this work is that urinary microRNA (found in all cells) may be useful as both biomarkers of overall liver injury and for the classification of specific toxicants.

Biomarkers for Cancer-Risk Assessment — NCTR scientists have demonstrated that exposure to chemical carcinogens results in altered gene expression. This altered gene expression may be used as biomarkers for cancer-risk assessment. These findings demonstrate different cancer-causing agents induce similar genetic alterations. These alterations typically appear early and correspond to those frequently found in tumor cells. The recognition that epigenetic or "gene-silencing" mechanisms can have a role in the development of cancer challenges the current approach to determine if a compound increases the risk of cancer. Studies continue at NCTR to: 1) develop biomarkers for

therapeutic approaches to clinical management of breast cancer, 2) establish biomarkers for pancreatic cancer, and 3) determine whether these biomarkers can detect reemergence of the disease before other invasive procedures are used.

Biomarkers of Drug-Induced Cardiotoxicity — NCTR continues research to develop molecular biomarkers for drug-induced heart damage that can be used to predict harmful effects of drugs during safety evaluations. Earlier detection of drug-induced cardiotoxicity is needed to reduce or reverse cardiac injury and improve therapeutic patient treatment.

Biomarkers for Pediatric Products — NCTR has been running parallel studies in zebrafish and nonhuman primates to identify critical biomarkers for studying pediatric products. An ongoing study using zebrafish has shown some compounds with little inherent toxicity, like L-carnitine, can have remarkable protective effects against the toxicities induced by general-anesthetic agents.

NCTR is developing positron emission tomography techniques to monitor aspects of neurotoxicity in animal models that can sometimes be associated with pediatric anesthesia. These techniques are providing information including location, duration, and intensity of toxicity and it is hoped they will eventually be useful in the clinical setting. These findings help the medical community understand the relationship between the amount, type, duration, and frequency of pediatric anesthetic use and its adverse effects on children. The expected outcome is to provide rapid-screening tests and understand pathways of toxicity to provide strategies for the safe use of pediatric anesthetics.

MicroArray Quality Control (MAQC) Consortium

NCTR began the MAQC project with participants from government, academia, and industry to establish uniform standards for conducting reproducible gene-expression experiments in the clinical setting and also by FDA reviewers. For more information visit: http://www.fda.gov/ScienceResearch/BioinformaticsTools/MicroarrayQualityControlProject/default.htm.

Since the inception of this FDA-led consortium, efforts have resulted in an FDA companion guidance document for data submissions involving pharmacogenomics and publication of 13 manuscripts in the prestigious *Nature Biotechnology* and *Pharmacogenomics Journal*. Findings from MAQC-II may lead to an FDA guidance document to aid industry in developing and validating microarray-based predictive models as biomarkers for diagnosis, prognosis, and toxicity assessment. The guidance will be a statistical “best practice” on utilizing microarray data and can be applied to all FDA-regulated products.

The Sequencing Quality Control (SEQC) project, led by NCTR, is the third phase of MAQC and aims to establish a baseline reference to standardize and streamline research using next-generation sequencing (NGS) technologies. This phase prepares FDA for the wave of genomic data submissions produced from NGS technologies to ensure the safety and efficacy of FDA-regulated products. In FY 2012, NCTR scientists completed

95% of the analysis of data generated from the SEQC project and developed nine manuscripts. Also in FY 2012, researchers used NGS technology to determine the sequences for small ribonucleic acids (RNAs) and discovered 14 previously unidentified rat microRNAs. The SEQC project teams are completing the data analysis and submitting their manuscripts for publication in scientific journals.

Computational Models to Predict Adverse Drug Reactions and Efficacy

NCTR is developing computational models to predict how effective a regulated drug will be or if serious adverse drug reactions can be anticipated based on a patients genetic make-up. These models may be implemented in an online knowledge base to alert reviewers, physicians, and patients of the potential for a drug to cause a serious adverse drug reaction in individuals carrying particular genetic variants before the drug is prescribed to the patient. These research studies can greatly enhance FDA's capability to detect, understand, predict, and prevent adverse drug reactions.

An NCTR and CDER collaborative study supports patient-specific genomic information and molecular modeling to understand, predict, and prevent adverse drug reactions. NCTR scientists developed models to understand the underlying mechanisms of adverse reactions related to Stevens Johnson syndrome and other drug-induced diseases. In FY 2012, analysis began with genomic-sequencing data received from the University of Liverpool that was collected from patients treated with cortisteroids and suffered adrenal suppression and/or cardiovascular disease. The data is being analyzed for associations between genetic variants — key information for predictive models.

Rapid-Detection Tools and Methodologies

Each year, hundreds of thousands of Americans are victims of food-related illness resulting in death or hospitalization according to the CDC. Data collected from NCTR research will help protect the food supply and may reduce economic burdens associated with foodborne illnesses by strengthening surveillance and risk analysis.

RAPID-B Method — NCTR developed and patented the RAPID-B method for real-time, on-site surveillance of food for bacterial contamination. NCTR has partnered with Vivione BioSciences for commercial development. Technical progress includes detecting bacteria in crops, seeds, and milk-carton paper. In FY 2012, NCTR scientists refined sample-processing techniques to detect target bacteria in difficult food products, such as peanut butter and milk. Not counting sample preparation, which can vary from zero to six hours, RAPID-B is capable of producing results in less than 15 minutes per sample. Preliminary work is being conducted to determine if RAPID-B can detect smaller infectious particles, such as prions (infectious proteins capable of reproducing on their own).

In FY 2012, NCTR scientists were awarded the FDA Commissioner's Challenge Grant for detecting Creutzfeldt-Jakob (CJD) prions in blood using RAPID-B. It is believed CJD, a form of brain damage leading to rapid decrease of mental function and movement, is caused by abnormal protein function. RAPID-B may be used to identify bacteria in blood that led to these and other diseases and researchers are validating this technique.

NCTR continues collaborative studies with CBER to extend the technique to targets other than bacteria, such as viruses, parasites, and even very small particles.

NCTR scientists have constructed a bacterial-pathogen knowledgebase (BACPAK). This information system supports research on foodborne bacterial-pathogen detection, characterization, and outbreak investigation. Currently, BACPAK contains microarray data, sequence data, PFGE (pulsed field gel electrophoresis) patterns and antimicrobial susceptibility data created by NCTR, CFSAN, CDC, and USDA on *Salmonella*. BACPAK also provides a new biostatistics tool to predict *Salmonella* serotypes based on a large dataset of 45,923 PFGE patterns. This new method provides a faster and more accurate prediction of *Salmonella* serotypes taken from outbreak samples than analysis by conventional methods. BACPAK and its accompanying biostatistics tools provide a platform for researchers to accelerate outbreak-strain identification and source tracking. Expansion of biostatistics tools is a continued focus at NCTR providing FDA with cutting edge knowledgebase capabilities.

Infrastructure to Manage Bioinformatic Data

Bioinformatics applies computer science and information technology to increase understanding of biological processes, and is a critical tool for scientific advancements. NCTR plays a key role for FDA in this scientific field. With increasing amounts of data being collected, it is essential that FDA have an electronic database to manage the voluminous amount of scientific data required for safety assessments and risk analysis. NCTR developed ArrayTrack™ to meet this demand. Initially used to manage gene-expression data, ArrayTrack™ is now used to review other data types and to provide the bioinformatic infrastructure for emerging sciences, such as pharmacogenomics (PGx) that focuses on clinical and safety biomarker identification with great potential for advancing medical product development. For more information visit:www.fda.gov/arraytrack.

NCTR expanded ArrayTrack™ to include a bioinformatics infrastructure called SNPTrack that supports PGx by helping understand the impact of genetic variation on drug treatment and personalized medicine. Reviewers have tested the beta-version in the review environment.

NCTR established a database of chemicals with endocrine disruptor activity data, known as the Endocrine Disruptor Knowledge Base (EDKB). The EDKB database is one of ten ArrayTrack™ libraries and contains roughly 8,000 chemicals that are suspected to introduce endocrine disruption in animals, including humans. NCTR scientists are developing a model to predict estrogen receptor binding activity which is considered a major mechanism for endocrine disruption. For more information visit: http://www.fda.gov/ScienceResearch/BioinformaticsTools/EndocrineDisruptorKnowledgebase/default.htm

ArrayTrack™ also contains a microbial library of over 270,000 gene records from 84 strains of foodborne pathogens and enables large datasets generated by NCTR

researchers and the analytical tests developed at CFSAN and USDA to be analyzed. ArrayTrack™ enables rapid identification of intestinal pathogens and their genetic traits, including antimicrobial resistance, virulence, and DNA fingerprints in outbreak investigations, supporting FSMA.

NCTR scientists will be investigating the potential for drug repositioning (or drug repurposing) using bioinformatics. Drug reposition is a process of finding new uses outside the scope of the original medical indications for existing drugs, which represents a new and promising direction to improve public health. The goal is to develop bioinformatics methodologies to repurpose marketed drugs with application on a) rare disease, b) specific complex diseases (e.g., Parkinson disease), c) replacing expensive drugs with inexpensive ones (e.g., over-the-counter drugs); and d) replacing unsafe drugs with safer ones.

NCTR has developed prototype of a Tobacco Constitute Knowledge Base (TCKB) for use by the Center for Tobacco Products (CTP) to manage the information related to harmful and potentially harmful constituents. Additionally, NCTR is establishing an Enclave environment for use by CTP to communicate data and information outside of the FDA regulatory network. Scientists developed a text-mining software to organize and analyze the documents submitted by the tobacco companies. The methodology behind the software has been demonstrated on three submissions.

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
263201: Develop science base for supporting FDA regulatory review of new and emerging technologies. *(Output)*	FY 2012: FDA/NCTR/ARL has established an extensive, fundamental nanotechnology materials core laboratory capable of characterizing the chemical and physical nature of nanoscale materials used in safety assessment studies (Target Met)	Establish and implement standard operating procedures (SOP) in research protocols for detection of nanoscale materials in FDA-regulated products in collaboration with ORA/Arkansas Regional Laboratory (ORA/ARL)	1) Define the miRNA biomarker genes that are associated with carcinogen exposure 2) Determine if biomarkers can be found to improve the detection of drugs and chemicals that cause liver injury	NA
262401: Develop biomarkers to assist in characterizing an individual's genetic profile in order to minimize adverse events and maximize	FY 2012: 1) A model of drug-induced heart damage was developed and is being used to identify new predictive biomarkers of early	1) Develop analytical methods to assess drug-induced heart damage 2) Identify target	Determine if some drugs cause a higher incidence of liver toxicity in women than men	NA

therapeutic care. *(Output)*	stages of drug-induced cardiac tissue injury. (Target Met) 2) Research experiments have been completed and preliminary results suggest the involvement of a number of genes involved in lipid metabolism and sugar transporters. (Target Met)	genes for obesity and the consequent development of metabolic syndrome diseases and heart disease		
264101: Develop risk assessment methods and build biological dose-response models in support of food protection. *(Output)*	FY 2012: Rapid B has expanded to include detecting bacteria in crops, seeds, and milk carton paper. (Target Met)	Expand Rapid B system to include new pathogen-specific (PS) assays (tests)	Identify an assay to detect infectious norovirus in contaminated foods	NA
263104: Use new omics technologies to develop approaches that assess risk and assure the safety of products that FDA regulates. *(Output)*	FY 2012: Knowledge base was formed and is being used to determine if interactions can be modeled via computer to improve drug development and assessment of individuals' risk to particular drugs. (Target Met)	Build a knowledge base to annotate existing drug-risk factor associations of immune-related drug reactions	Determine if miRNA(found in easily-obtained body fluids) exhibit superior biomarker properties that can be used for indicating drug induced liver injury	NA
263102: Develop computer-based models and infrastructure to predict the health risk of biologically active products. *(Output)*	FY 2012: Models were developed and results indicated that the 3D-QSDAR approach can provide more reliable results than alternative approaches.(Target Met)	Develop 3D/4D Quantitative Spectrometric Data-activity Relationship (QSDAR) models for predicting endocrine disruptor activity	Find new uses for existing and abandoned drugs	NA

Information Technology Investments – National Center for Toxicological Research Activities (Base Amount displayed as a non-add item: $8,167,806)

FDA modernized and enhanced its information technology (IT) infrastructure to provide a state of the art, secure technological foundation to support all FDA programs. This newly completed effort provides a foundation on which FDA may improve its capabilities and enhance its ability to perform its scientific and regulatory mission. FDA's agency-wide costs associated with the operation and maintenance of this shared IT infrastructure includes two data centers, telecommunication networks, IT security and help desk functions. In addition, each center and office has program specific IT systems and is

supported by enterprise systems ranging from improving the premarket review process for all regulated products to post-market surveillance, including adverse event detection, and future scientific computing capabilities This common infrastructure facilitates consolidation and meets E.O.13514 related to energy efficiency, HHS and OMB mandates with respect to green computing, cloud computing, and virtualization.

Science management, via information technology, plays a vital role in helping FDA achieve its mission in protecting and advancing public health. The pace of scientific discovery places a high-demand on the Agency to maintain awareness of all the current trends and latest developments. Within this realm of responsibility, scientists are constantly challenged with introducing new and innovative scientific-computing initiatives and streamlining data management processes. NCTR will expand the Agency's commitments to the scientific information technology advancement trend by:

- Focusing on developing new IT scientific platforms, for example, Knowledge Base initiatives in such areas as drug-induced liver injury. These knowledge bases will enrich the regulatory desktop with tools to carry out integrative analyses across multiple data types in search of safety signals.
- Developing analysis and modeling methods in the fields of toxicology, biochemistry, and genomics, as well as other methods of data exploration, including statistics, artificial intelligence, and genetic algorithms. Also within the field of scientific computing, NCTR maintains the venue to develop innovative technologies that will further advance personalized medicine.
- Expanding existing platforms such as the NCTR-developed ArrayTrack™ — an integrated DNA microarray data management, mining, analysis, and interpretation software system — to allow for the addition of new capabilities to handle priorities and evolving technologies.

One such expansion will be used to support Pharmacogenomics (PGx) research that requires a bioinformatics infrastructure to review and understand how sponsors reach their biological conclusions. Special IT networks will enable collaborative interoperability with the external scientific community, leveraging FDA science efforts and providing for the collection of more data to support science-based risk/benefit assessments.

These IT initiatives will enhance the research efforts of interdisciplinary scientists who conduct peer- reviewed research essential to identifying health and safety issues related to new and existing FDA-regulated products.

Funding History Table with FTE Totals

The following table displays funding and full time equivalent (FTE) staff levels from FY 2010 through FY 2013 for NCTR, plus the FY 2014 request.

Fiscal Year	Program Level	Budget Authority	Program Level FTE
FY 2010 Actual	$58,531,000	$58,531,000	246
FY 2011 Actual	$60,563,000	$60,563,000	272
FY 2012 Actual	$60,039,000	$60,039,000	269
FY 2013 CR	$60,406,000	$60,406,000	273
FY 2014 Request	$59,494,000	$59,494,000	272

Summary of the Budget Request

The FY 2014 budget request for the National Center for Toxicological Research (NCTR) Program is $59,494,000. This amount is a decrease of $545,000 below the FY 2012 Enacted Level. The NCTR amount supports 272 FTE.

The base funding for the NCTR Program is $60,039,000 which is used for NCTR research activities.

Base funding allows the NCTR Program to advance the FDA mission of ensuring that FDA-regulated products available to the American public are safe and effective. This mission is accomplished by conducting research on the risks and benefits of the full spectrum of FDA regulated products; animal and human drugs, devices, cosmetics, biologics and tissues, tobacco, and ensuring food safety.

At this funding level, NCTR will conduct innovative research and develop new tools, standards, and approaches to assess the safety, efficacy, quality and performance of regulated products. NCTR research integrates comprehensive toxicology safety assessments maximizing existing and emerging technologies. NCTR will continue research in the priority areas of nanotechnology, bioinformatics to better utilize:

- Scientific data
- Pediatric product development and safety assessments
- Noninvasive bio-imaging
- Translation of biomarkers of toxicity from the animal model to the human model.

Another priority area for NCTR and FDA is to provide regulatory science training and counsel to the global research community through both domestic and international outreach programs.

Budget Details Request

Adjustment to Base (Total Program: -$545,000 and +3 FTE)

The budget request for $59,494,000 in total budget authority for the NCTR Program reflects a reduction to the base of -$808,000 for FY 2014 and a pay increase of +$263,000 with no change in FTE.

Evaluating Toxicity of FDA Regulated Products

Center Activities –
FY 2012 Enacted Base (100% BA): $22,076,102
FY 2014 Total Change from Base: (-$200,397)/+1 FTE)

Modernizing Toxicology to Support the FDA Mission

Center Activities –
FY 2012 Enacted Base (100% BA): $37,962,898
FY 2014 Total change from Base: (-$344,603)/+2 FTE)

NCTR Performance Activity Data (PAD)

The following table lists the NCTR Program Activity Data (PAD) over a three year fiscal period.

NCTR Workload and Outputs	FY 2012 Actual	FY 2013 Estimate	FY 2014 Request
RESEARCH OUTPUTS			
Research Publications	187	173	182
Scientific Presentations	175	166	158
Patents (Industry)	5	5	5
LEVERAGED RESEARCH			
Federal agencies (Interagency Agreements)	4	3	6
Nongovernmental organizations	10	13	16

ACTIVE RESEARCH PROJECTS			
Personalized Nutrition and Medicine	45		
Strengthen Surveillance & Risk Analysis	26		
Enhancing Product Safety	91		
NEW FY13 Program: Evaluating Toxicity of FDA-Regulated Products		55	57
NEW FY13 Program: Modernizing Toxicology To Support the FDA Mission		116	94
Total Active Research Projects	***162***	***171***	***151***

Field Activities – Office of Regulatory Affairs

The following table displays funding and full-time equivalent (FTE) staffing levels for FY 2012 through FY 2014.

FDA Program Resources Table
(Dollars in Thousands)

	Enacted	Actuals	FY 2013[1] CR	FY 2014 Request	+/- FY 2012
Program Level	**$960,745**	**$931,778**	**$1,019,992**	**$1,217,008**	**+$256,263**
Program Level FTE	**4,675**	**4,451**	**4,769**	**5,255**	**+804**
Budget Authority	**$905,735**	**$906,768**	**$911,279**	**$917,329**	**+$11,594**
Budget Authority FTE	**4,478**	**4,343**	**4,406**	**4,483**	**+140**
User Fees	**$55,010**	**$25,010**	**$108,713**	**$299,679**	**+$244,669**
PDUFA	$14,225	$8,265	$14,656	$15,489	+$1,264
FTE	56	53	53	53	0
MDUFMA	$1,572	$2,028	$1,582	$2,105	+$533
FTE	13	13	13	11	-2
ADUFA	$315	$141	$317	$472	+$157
FTE	2	1	1	1	0
AGDUFA	$160	0	$161	$220	+$60
FTE	1	0	1	1	+1
MQSA	$13,077	$9,135	$13,077	$13,077	0
FTE	8	8	8	8	0
Center for Tobacco Products	$6,250	$5,441	$6,288	$14,989	+$8,739
FTE	26	33	41	70	+37
Food Reinspection	$9,375	0	$9,433	$9,800	+$425
FTE	66	0	66	66	+66
Recall User Fee	$10,036	0	$10,098	$10,491	+$455
FTE	25	0	25	25	+25
Medical Products Reinspection [2]	0	0	0	$7,170	+$7,170
FTE	0	0	0	46	+46
Generic Drugs	0	0	$51,811	$53,023	+$53,023
FTE	0	0	150	173	+173
Biosimilars User Fee	0	0	$1,290	$1,322	+$1,322
FTE	0	0	5	5	+5
Cosmetics User Fee [2]	0	0	0	$4,407	+$4,407
FTE	0	0	0	18	+18
Food Registration and Inspection [2]	0	0	0	$27,855	+$27,855
FTE	0	0	0	22	+22
Food Import User Fee [2]	0	0	0	$134,355	+134,355
FTE	0	0	0	253	+253
International Courier Fee [2]	0	0	0	$4,904	+$4,904
FTE	0	0	0	20	+20
User Fees FTE	**197**	**108**	**363**	**772**	**664**

[1] Spending authority has been adjusted pursuant to PL 112-175, Section 101(c) for the applicable user fee programs.

[2] Proposed user fee.

Authorizing Legislation:

The Office of Regulatory Affairs (ORA) plans and directs the management and administration of personnel and facilities to ensure that the Federal laws and regulations regarding FDA regulated products are enforced. Specifically, FDA administers the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, et seq. (FFDCA), and designated sections of the Public Health Service Act.

ORA directs field operations that several thousand FDA scientific, regulatory, and consumer safety personnel perform throughout the Nation and abroad. ORA also manages state-of-the-art scientific laboratories strategically located throughout the United States and in Puerto Rico to support the FDA mission.

In addition, the Secretary of the Department of Health and Human Services (HHS) delegated to the Commissioner of FDA the functions vested in the Secretary under the following statutes and orders:

Filled Milk Act (21 U.S.C. §§ 61-63)
Federal Import Milk Act (21 U.S.C. § 141, et seq.)
Federal Caustic Poison Act (44 Stat. 1406)
The Fair Packaging and Labeling Act (15 U.S.C. 1451, et seq.)
Comprehensive Drug Abuse Prevention and Control Act of 1970 (84 Stat. 1241)
Controlled Substances Act (21 U.S.C. § 801, et seq.)
Federal Meat Inspection Act (21 U.S.C. § 679(b))
Poultry Products Inspection Act (21 U.S.C. § 467f(b))
Egg Products Inspection Act (21 U.S.C. § 1031, et seq.)
Executive Order 11490, § 1103
Federal Advisory Committee Act (5 U.S.C. Appx. 2)
Lead-Based Paint Poisoning Prevention Act (42 U.S.C. § 4831(a))
Small Business Act (15 U.S.C. § 638)
Consumer-Patient Radiation Health and Safety Act of 1981 (42 U.S.C. §§ 10007 and 10008)
Patent Term Extension (35 U.S.C. § 156)
Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. § 3701, et seq.) and Executive Order 12591
Pesticide Monitoring Improvements Act of 1988 (21 U.S.C. §§ 1401-1403)
Food, Agriculture, Conservation, and Trade Act of 1990 (7 U.S.C. §138a)
Effective Medication Guides of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 1997 (Public Law 104-180)
Equal Access to Justice Act (5 U.S.C. § 504)
Best Pharmaceuticals for Children Act (Public Law 107-108), as amended by Pediatric Research Equity Act of 2003 (Section 3(b)(2) of Public Law 108-155)
The Office of Criminal Investigations (OCI) of ORA conducts criminal investigations and executes search warrants as permitted by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 372), the Public Health Service Act (42 U.S.C. 262) and the Federal Anti-

Tampering Act (18 U.S.C. 1365).

Allocation method: Direct Federal/Intramural

Program Description and Accomplishments

ORA is one of two offices under the Office of Global Regulatory Operations and Policy (OGROP). The second office under OGROP is the Office of International Programs. ORGOP provides executive oversight, strategic leadership, and policy direction to FDA's domestic and international product quality and safety efforts, including global collaboration, global data-sharing, development and harmonization of standards, field operations, compliance, and enforcement activities.

ORA is the lead office for FDA field activities and advises FDA leadership on imports, inspections, and enforcement policy. ORA field activities support the six FDA product centers by assessing industry compliance with applicable laws and regulations to protect public health. To assess industry compliance, ORA:

- Inspects manufacturers and conducts examinations of regulated products,
- Conducts sample analysis on regulated products,
- Reviews imported products offered for entry into the United States for both security and admissibility,
- Executes the FDA Import Strategy and Food Protection Plans,
- Directs and coordinates FDA emergency preparedness and response programs,
- Develops FDA-wide policy on compliance and enforcement, and
- Provides State inspection staff with ORA-sponsored training courses.

ORA maintains offices in Washington, D.C., the U.S. Virgin Islands, Puerto Rico, and all States except Wyoming.

ORA supports approximately 4,600 FTE throughout the Unites States. More than 79 percent of ORA staff is stationed in five regional offices, 20 district offices, 13 laboratories, and 172 resident posts and border stations.

As a separate entity within ORA, OCI personnel are located in 30 field, resident, and domicile offices throughout the United States.

In addition to its Federal workforce, ORA works with State, local, tribal, and territory counterparts to further FDA's mission. ORA funds contracts, grants, and cooperative agreements to enable the States to perform inspections and to provide technical assistance in such areas as milk, food, and shellfish safety. State inspection staffs attend and participate in ORA-sponsored training courses.

ORA is an enterprise-wide organization that performs activities across all major FDA initiatives, including: Transforming Food Safety and Nutrition, Protecting Patients,

Globalization, FDA Regulatory Science, and Facilities. However, to be consistent with the budget presentation in this Performance Budget, the program description and accomplishments section below is thematically subdivided into six parts according to the six FDA product centers: Foods, Drugs, Biologics, Animal Drugs and Feeds, Devices and Radiological Health, and Tobacco.

Foods – Field Activities
Base Amount: $617,049,000 (BA: $600,827,000 / UF: $16,222,000)

ORA field offices support Foods Program activities by developing FDA-wide compliance and enforcement policy and executing FDA's Import Strategy and Food Protection Plans. Through its field offices nationwide, ORA conducts domestic and foreign inspections of food manufacturers, sample analyses on regulated food products and import security and admissibility reviews, field examinations, and verification inspections using risk-based strategies. ORA collaborates with State, local, tribal, and territory counterparts to further FDA's food safety mission by funding contracts, grants, and cooperative agreements to perform State food inspections, support the capacity building of State, local, tribal, and territory regulatory counterparts, and provide State inspection staff with ORA-sponsored training courses.

ORA executes its Foods Program regulatory responsibilities in five subprogram areas:

- Prioritizing Prevention
  Base Amount: $111,373,000 (BA: $111,373,000 / UF: $0)
- Strengthening Surveillance
  Base Amount: $286,015,000 (BA: $286,015,000 / UF: $0)
- Strengthening Enforcement
  Base Amount: $167,081,000 (BA: $150,859,000 / UF: $16,222,000)
- Improving Response and Recovery
  Base Amount: $49,327,000 (BA: $49,327,000 / UF: $0)
- Reinventing Cosmetics Safety
  Base Amount: $3,253,000 (BA: $3,253,000 / UF: $0)

Detailed information on subprogram-specific activities appears in the Foods tab in this budget that displays the FDA Foods Program narrative.

Public Health Focus

The food supply is part of the Nation's critical infrastructure and contributes approximately 20 percent to the U.S. Gross National Product. A terrorist attack on the food supply could have catastrophic public health and economic consequences.

The challenges facing ORA regarding food safety are daunting. FDA regulates $417 billion worth of domestic food, $49 billion worth of imported foods, and more than $60 billion worth of cosmetics sold across State lines. This regulation takes place from the

products' point of U.S. entry or processing to their point of sale. There are more than 377,000 registered food facilities (including approximately 154,000 domestic facilities and 223,000 foreign facilities) that manufacture, process, pack, or hold food consumed by humans or animals in the United States and several thousand cosmetic firms.

Increased globalization and complexity of the food supply chain is a major challenge to ensuring the safety of imported products. Globalization is primarily responsible for the ever-increasing volume and diversity of foods entering the United States. Between 10% and 15% of all food consumed by U.S. households is imported from abroad. According to the U.S. Government Accountability Office nearly two-thirds of fruits and vegetables and 80% of seafood consumed domestically come from outside the United States

To advance public health and protect consumers, ORA focuses on prevention through outreach coordination and technical assistance. To gain expertise and encourage collaboration with external stakeholders, internal and extramural training remains a top priority.

ORA devotes resources to the prompt and efficient response to foodborne outbreaks and events. ORA conducts import entry reviews for both security and admissibility requirements, import field examinations, import sample collections, and laboratory analyses. One of ORA's primary duties is to perform risk-based inspections of food producers and provide a strong, effective, and efficient enforcement of FDA laws and regulations. ORA investigators conduct physical inspections of regulated domestic and foreign food establishments. Examples of ORA food inspection programs include domestic food safety, imported and domestic cheese, domestic low acid canned foods, domestic fish and fishery products Hazard Analysis & Critical Control Points (HACCP), import seafood HACCP, juice HACCP, and interstate travel sanitation. Risk based inspections are vital for protecting the Nation's food supply.

ORA also identifies and develops new investigational resources, tools, and training programs while establishing an infrastructure that supports continued effective and efficient response. As FDA continues to move forward in meeting national food defense goals, it relies on States and local health agencies to assist in improving preparedness and response activities. Grant and cooperative agreement funds allow States and counties to increase efficiency in the areas of response, prevention, and intervention in addition to enlarging the nationwide pool of resources to strengthen food defense and mitigate safety issues.

FDA Food Safety Strategy

The FDA Foods and Veterinary Medicine Program (FVM) Strategic Plan 2012 – 2016 can be found at the following FDA web link:
http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofFoods/UCM273732.pdf

ORA achieves the overall FDA Food Safety and Modernization Act (FSMA) strategy by focusing on preventing food safety problems rather than reacting to problems after they occur. These activities are part of the FVM *Strategic Plan* goals of establishing science-based preventive control standards and regulations across the farm-to-table continuum to protect the food and feed supply from contamination. This is accomplished by identifying the most significant foodborne contaminants and evaluating the effectiveness of existing controls for those contaminants.

ORA achieves food safety goals by enhancing risk-based decision making, developing metrics for risk-based food safety priority setting, collaborating on the development and implementation of the model for evidence-based resource planning, and most importantly conducting risk-based domestic and foreign food safety inspections.
ORA also maintains and strengthens mission-critical science capabilities, administers centralized planning and performance measurement, facilitates information sharing internally and externally including effective communication of research plans and knowledge gaps, implements new enforcement tools, devises mechanisms for assuring that imported foods and feeds meet preventive controls standards, and collaborates with State, local, tribal, and territorial officials and staff on inspection and compliance efforts.

ORA contributes to achieving Response and Recovery goals by investigating and adopting innovative technologies and processes to detect and investigate such events, enhancement of the Reportable Food Registry, and effective risk communications related to outbreaks and contamination incidents. ORA is able accomplish this by responding to issues that occur across the farm-to-table continuum and analyzing outbreaks and lessons learned from response to improve FDA activities at the other stages.

ORA provides coverage of the rapidly expanding import and domestic cosmetic programs by conducting inspections and sample analyses on products in order to prevent unsafe cosmetics or ingredients from reaching consumers in the United States.

Public Health Outcome

In FY 2012, ORA participated in outreach events at a variety of public meetings, symposiums, and conferences that were attended by regulated industry, other government agencies, and foreign regulatory bodies.

The FDA Compendium of Microbiological Protocols and Chemical Tests, a compilation of analytical detection methods for foods designed to support the mission of FDA housed within the Electronic Laboratory Exchange Network (eLEXNET), released a new method in FY 2012 – "Detection of Toxic Elements" – and made it available to the chemistry community. eLEXNET added three new labs in FY 2012 and successfully completed the initial phase of a data sharing pilot with Canada Food Inspection Agency and Health Canada.

ORA provided funding through a cooperative agreement to 26 State food regulatory programs to support implementation of the Manufactured Food Regulatory Program Standards (MFRPS). At the end of FY 2012, a total of 41 programs in 40 States were enrolled in MFRPS. ORA conducted 44 visits with States to assist in their implementation of the standards and 11 State assessments to determine the States' progress in implementing MFRPS. ORA funded 31 State regulatory program laboratories and a laboratory association (APHL) under two cooperative agreements to provide support, best practices, and training for laboratories to achieve International Organization for Standardization accreditation. By working with these public health partners, FDA is establishing a fully integrated food safety system (IFSS) to prevent foodborne illness through the adoption and uniform application of model programs, like MFRPS and other applicable program standards.

In FY 2012, ORA provided funding through a cooperative agreement to 38 State, local, county, and city regulatory agencies to support implementation of the Voluntary Retail Program Standards. This cooperative agreement funding provides the means for these programs to build their capacity, capability, and infrastructure to increase implementation of the retail standards and better protect public health.

In 2012, the Egg Safety Rule went into effect for smaller shell egg producers, those with between 3,000 and 49,999 laying hens. FDA began outreach efforts for this industry segment and implemented inspections of these smaller shell egg producers. Contracts were issued with eight State partners to conduct inspections of these facilities.

FDA awarded seven training grants to enhance the ability of the grantee to design, develop, and deliver food safety training and personnel certification programs by leveraging the expertise of universities, professional trade associations, and non-profit organizations. Over 70 grant projects contribute to the development and implementation of IFSS. The training and certification programs also support MFRPS and the Retail Food Regulatory Program Standards.

In FY 2012, ORA continued its usage of its chemistry and microbiological mobile laboratories in support of FDA's food defense initiatives and surveillance of import and domestic produce. The microbiological mobile lab deployed on three separate occasions where 2,185 imported and domestic samples comprised of 21,850 sub-samples with a history of association to foodborne-outbreak illnesses were analyzed for enterohemorrhagic E. coli and *Salmonella*. Eleven samples were confirmed positive for *Salmonella* and one was confirmed positive for Shiga toxin 2. An automated high-throughput molecular platform was put in place for the 2012 deployments to advance the mobile lab's technological capabilities. This new platform effectively increased the mobile lab's analytical throughput by 50 percent. In addition, an effort to enhance the self-contained nature of the laboratories, the microbiological mobile laboratory initiated preparation of media in-house and confirmation of any "cannot rule out" sample for microbial adulteration. These additional procedures allowed the mobile lab to operate predominately independent of a fixed site lab.

In May 2012, FDA issued a pilot food defense assignment in preparation for the national elections that involved inspections and collections based on food defense risk assessment models. ORA utilized the Food Emergency Response Network (FERN) cooperative agreement laboratories to analyze multiple matrices and analytes of food defense concern. FERN labs tested 143 radiological samples, 119 microbiology samples, and analyzed 154 chemistry samples. All results were successfully reported in a timely manner. Feedback from the pilot assignment was used to strengthen and update the surveillance performed during the republican and democratic national conventions. During those assignments there were a total of 32 chemistry, 34 microbiology, and 41 radiochemistry samples analyzed. Overall, the FERN labs analyzed more than 500 samples. This assignment strengthened the communication and response of laboratories nationwide to respond to chemical, microbiological, or radiochemical threats to the Nation's food supply in a politically tense and highly populous event situation.

In FY 2012, ORA implemented use of two different handheld devices throughout the Nation. One of the tools allows ORA investigators to screen imported dietary supplements for the presence of Active Pharmaceutical Ingredients (APIs). After screening more than 200 products, ORA investigators found 44 of the products screened positive for the presence of APIs. Full analyses performed by ORA laboratories found all 44 products contained Sibutramine. Sibutramine substantially increases blood pressure and pulse rate and may present a significant risk for people with a history of coronary artery disease, congestive heart failure, arrhythmias, or stroke. ORA subjected the products to detention and worked with U.S. Customs and Border Protection (CBP) to seize these shipments, keeping these dangerous products out of the U.S. market.

Historically ORA focused on import products as they tend to exhibit a higher violation rate than domestic products. However, the increased surveillance in domestic products in response to a European Union audit recommendation provided a unique opportunity to take a snapshot of the chemical contaminant profile exhibited by select domestic products. The increased surveillance started in FY 2012 and is carrying over into FY 2013. The increased surveillance targets collection of approximately 800 distinct samples and testing of each of these samples for a number of families of compounds including pesticides, persistent organic pollutants, metals, and mycotoxins. The activity produces thousands of analytical data points and gives an expansive overview of the residue testing profile of the targeted domestic products.

A Nanotechnology Core Facility involving the ORA Arkansas Regional Laboratory (ARL) and the National Center of Toxicology Research became fully operational in 2012. This facility provides the necessary analytical tools and advanced imaging equipment to adequately characterize nanoscale materials within multiple FDA regulated product classes. Scientists at ARL have developed a method to screen dietary supplements for

total silver content using a portable analytical tool. As silver is the most widely used nanomaterial in consumer products, this method has allowed ORA to expand its laboratory capabilities and strengthen its ability to make science-based regulatory decisions.

During FY 2012, ORA performed field and label examinations on more than 190,000 entry lines of food related products, refused more than 14,000 entry lines of violative food related products, and issued 56 Import Bulletins increasing the FDA's field surveillance over suspected food products. Those activities are performed to identify readily visible violations such as verification that the product labeling meets applicable compliance requirements or determine the presence of macro filth. Physically verifying that refused entry lines are exported or destroyed is imperative to the protection of public health, ensuring that refused products are prevented from reaching U.S. consumers.

ORA completed full national rollout of Mission Accomplishment and Regulatory Compliance Services (MARCS) Imports Entry Review (ER) and Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) to all 16 import Districts. MARCS Imports ER is FDA's new application to make initial admissibility decisions, assign field work, and display the results of the PREDICT risk-based screening and database lookups. PREDICT screens all lines of imported product electronically submitted to FDA via a CBP interface. PREDICT is designed to calculate a customized risk score for every line in an entry based on a number of factors including inherent risk of the product, data anomaly rules, data quality rules, and the compliance history of the firms manufacturing or shipping the product. PREDICT also has automated database lookups linked to data stored in FDA center databases, such as a firm's registration, product listing and approval status.

ORA's Division of Food Defense Targeting (DFDT), formerly known as the Prior Notice Center, was established in response to regulations promulgated in conjunction with the Public Health Security and Bioterrorism Preparedness Act of 2002. DFDT carries out its role to protect U.S. consumers from an intentional threatened or actual terrorist attack on the U.S. food and feed supply. ORA performed more than 81,000 prior notice reviews of food and feed in FY 2012. Every prior notice is electronically screened and targeted and all those identified as high risk receive an intensive security review.

Under the FSMA Smuggled Food/Feed Strategy, ORA collaborated with CBP in targeting and conducting examinations of import shipments to identify and take enforcement action against those found to contain smuggled food and feed products. Smuggled food and feed presents a hazard to consumers and its entry erodes confidence in the safety of the food and feed supply. ORA and CBP conducted more than 1,000 examinations under this strategy and have taken action when appropriate, including the seizure of smuggled shrimp and peppers in FY 2012.

ORA performed 1,347 foreign food establishment inspections in 36 countries compared to 1,003 foreign food inspections conducted during the same period in FY 2011, a 34

percent increase. In FY 2012, an inspection of a foreign seafood processor revealed serious violations of the seafood HACCP regulation. The inspection noted that the firm's HACCP plan for tuna failed to list adequate monitoring procedures and frequencies to control histamine formation and *Clostridium botulinum* growth and potential toxin formation. As a result of this inspection, ORA took regulatory action and issued a Warning Letter to the firm.

FDA uses risk factors to target firms to inspect, focuses the on-site inspections in the most critical areas, and continues to leverage the work of our dedicated foreign inspection cadre and FDA inspection staff located at FDA's foreign offices, and our district-based investigators to enhance overall coverage of the foreign establishment inventory. An inspection of a foreign chocolate manufacturer revealed that the firm had shipped 216 cases of chocolate bars to the United States from a lot that tested positive for *Salmonella risen*. As a result of this finding, the U.S. distributor was visited and the entire shipment was placed on hold thereby preventing the potentially contaminated chocolate bars from reaching the U.S. consumer.

ORA awarded food inspection contracts to State agencies and territories. These contracts enhance an integrated food safety system by providing States and territories with funding to perform basic Good Manufacturing Practices (GMP) inspections as well as inspections in high risk industries such as juice and seafood under HACCP and low acid canned foods and acidified foods.

The 41 State programs currently enrolled in MFRPS conduct 96 percent of all GMP inspections performed under FDA contract. ORA created the Manufactured Food Regulatory Program Alliance through a cooperative agreement to provide additional resources, training, and support to programs that are implementing the standards. In FY 2012, FDA issued contracts with eight State programs to complete inspections under the Egg Safety Rule. In FY 2012, ORA saw 56 jurisdictions newly enroll in the voluntary retail program standards. Currently, 534 jurisdictions are enrolled.

In FY 2012, there were nine injunctions and five seizures against food and dietary supplement processors and manufacturers. These enforcement actions protect consumer safety by assuring that processors and manufacturers comply with laws and violative food and dietary supplement products are not distributed into commerce.

FDA classified 317 Class I, 306 Class II, and 75 Class III recalls of food products. ORA monitors recalls of food products and ensures the effectiveness of the firm's recall to remove the defective product from commerce.

During FY 2012, ORA's OCI made 37 arrests, and secured 32 convictions with fines, restitutions, and other monetary penalties in excess of $9.8 million. Representative cases include:

Adulterated cheese: In April 2012, four individuals from Mexico, Illinois, and Wisconsin were indicted on charges for conspiring to ship and distribute more than 110,000 pounds of Mexican cheese throughout the United States after FDA detained and ordered the cheese to be held for inspection. The cheese was later determined to be adulterated with *Salmonella*, *E. coli*, and other illness-causing bacteria. The four defendants scraped off mold and fungus from cheese returned by dissatisfied customers, re-sold it, and later lied to an FDA inspector to cover up the illegal redistribution/sales of the adulterated cheese. The four defendants owned or worked for companies responsible for importing and manufacturing the cheese.

Prickly pear: In California a group of import brokers were engaged in a scheme to defraud FDA. They helped customers import goods barred by FDA, including produce infected by *Salmonella* Agona, a life-threatening infectious bacteria. On one occasion, after a shipment of nopal cactus (also known as prickly pear) tested positive for *Salmonella*, coconspirators illegally changed the description of the nopal cactus' grower for subsequent shipments, for the purpose of evading future FDA inspections. Similarly, other offenders conspired to import Mexican snack foods that were mislabeled and adulterated with a prohibited dye.

ORA partners with public and private entities to leverage data sharing and personnel. Examples of these FDA outreach partnerships include State contracts, FERN laboratories, rapid response and State lab cooperative agreements, Partnership for Food Protection, Food Protection Task Force grants, and 50 State meetings. In FY 2012 FDA funded the expansion of the rapid response teams (RRTs) cooperative agreement with the inclusion of new States into the program.

In FY 2012, ORA provided funding to 36 State, local, tribal, and territorial partners to support capacity building in the areas of recalls and inspections in support of Section 210 of FSMA. This work enables Federal and State partners to improve their systems to quickly and effectively stop an outbreak and mitigate the concern. ORA supported the newly formed Coordinated Outbreak Response and Evaluation (CORE) organization, which was formed specifically to improve FDA's response to foodborne illness outbreaks. In FY 2012, a multi-agency Incident Management Group was formed comprised of FDA, the Centers for Disease Control and Prevention (CDC), and numerous State Health Agencies to investigate a nationwide *Salmonella* outbreak. The group was able to identify a specific foreign supplier of ground tuna suspected to be the source of the outbreak and remove the contaminated product from commerce. FDA worked with the foreign competent authority, which subsequently closed the firm following a violative inspection.

The globalization of the U.S. food supply, rapid and widespread distribution of food, and changes in consumer expectations create the need for a framework for food protection. Protecting the U.S. food supply requires an integrated approach for recognizing, investigating, and responding to foodborne illnesses. In FY 2012, ORA worked with

States to establish new and develop further existing RRTs, comprised of both ORA and State inspectors. An additional ten RRTs were funded by the end of FY 2012, which results in a total of 19 RRTs.

ORA scientists developed collaborations with assachusetts, New Hampshire, and Vermont to extend and enhance the much needed capability of surveillance testing for radionuclides in food samples. The Federal-State collaboration involved the collection and analysis of fish samples from these States for the presence of radionuclides. The study provided a baseline measurement for current and future comparisons and addressed the public's health concern of radionuclide contamination.

FDA also continued its increased surveillance of Japanese food products under Import Bulletin 99-B38, and provided a network of coverage to ensure no radiation-contaminated product reaches U.S. consumers. Through the middle of July 2012, ORA field offices conducted more than 7,000 examinations, and ORA field laboratories analyzed more than 200 samples, with no objectionable findings. In July it was determined this level of increased surveillance was no longer warranted; however, routine coverage of products continues under existing programs.

In FY 2012, a U.S foodborne outbreak of *Listeria monocytogenes* was associated with cantaloupes. The outbreak sickened many people causing hospitalizations and deaths. ORA investigators, in collaboration with Center for Food Safety and Applied Nutrition, CORE, CDC, and State and Local health agency staff, conducted an investigation at the implicated farm and collected samples of cantaloupes as well as environmental samples at areas of interest. ORA field laboratory analysis confirmed the presence of L. monocytongenes in the cantaloupes, and FDA was able to work with the domestic farm to issue a recall. FDA and CDC collaborated and updated the events on web postings, providing consumer guidance on proper cleaning and sanitizing of refrigerators, food contact surfaces, and utensils. These activities have improved FDA's response to outbreaks.

In FY 2012, ORA responded to findings reported to FDA of a pesticide residue, carbendazim, in orange juice and orange juice concentrates. Carbendazim is a broad-spectrum fungicide but does not have an established tolerance in oranges. Therefore, its presence in oranges, orange juice, or orange juice concentrates constitutes a violation of the Environmental Protection Agency (EPA)-established pesticide regulations. ORA tested 163 shipments of imported orange juice or orange juice concentrates over a three month period spanning January through March 2012. Out of these 163 shipments, 31 shipments were found to contain violative levels of carbendazim and were refused entry into the United States.

ORA is developing a Laboratory Information Management System (LIMS) that seeks to improve the capability of the ORA regulatory laboratories to provide the necessary evidence tracking and effective sample management throughout the analytical process. LIMS is a nationwide automated system that corrects a major shortcoming in the ways

that ORA laboratories process and report on assigned samples. LIMS is capable of electronically capturing, storing, and reporting data pertaining to laboratory operations. LIMS provides the information technology enhancements to increase performance and the efficiency of the ORA laboratory operations. ORA began preparations for user acceptance testing (UAT) and training of the LIMS at four of the ORA laboratories in FY 2012 with an anticipated production release in seven of the 13 labs by the end of FY 2013.

ORA made the Import Trade Auxiliary Communications System (ITACS) available to the public. ITACS is an internet portal that provides the import community information for targeted shipments and the ability to check the status of individual entries and to submit entry documentation. ITACS enhances the entry review process by making available to the import community the information electronically and by improving communication with ORA field offices.

ORA issued more than 55 cosmetics-related notices identifying Import Alerts encompassing violations from microbiological contamination to non-permitted or undeclared color additives. These actions were a result of ORA import surveillance collections and testing of regulated cosmetic products at the time they were offered for import into the United States. These notices serve to provide increased coverage at the border to assure these products are not available to the U.S. consumer.

CDC notified FDA that *Mycobacterium Chelonae* was identified from skin biopsies samples that were taken from rashes on tattooed areas of people's bodies. The outbreak was far reaching with 26 confirmed cases in five States. ORA investigators performed numerous inspections of tattoo establishments, gathering information, and collecting tattoo ink samples as well as environmental samples in the establishments. Laboratories are analyzing the samples to help identify the source of the contamination and the investigation is ongoing.

Performance Measures

The following tables list the performance measures associated with this program.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
214201: Number of prior notice import security reviews. *(Output)*	FY 2012: 81,888 Target: 80,000 (Target Exceeded)	80,000	80,000	Maintain
214202: Number of import food field exams. *(Output)*	FY 2012: 171,783 Target: 160,000 (Target Exceeded)	160,000	160,000	Maintain

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
214203: Number of Filer Evaluations. *(Output)*	FY 2012: 1,338 Target: 1,000 (Target Exceeded)	1,000	1,000	Maintain
214204: Number of examinations of FDA refused entries. *(Output)*	FY 2012: 10,229 Target: 7,000 (Target Exceeded)	7,000	7,000	Maintain
214206: Maintain accreditation for ORA labs. *(Outcome)*	FY 2012: 13 labs Target: 13 labs (Target Met)	13 labs	13 labs	Maintain
214205: As required by the FSMA Legislation, cover 100% of the High Risk domestic inventory (approximately 22,000 firms) every three years. *(Output)*	FY 2012: 85%* (Historical Actual)	NA	33%	NA
214305: Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week). *(Outcome)*	FY 2012: 2,500 rad & 2,100 chem Target: 2,500 rad & 2,100 chem (Target Met)	2,500 rad & 2,100 chem	2,500 rad & 2,100 chem	Maintain

*The assumed FY 11 target would have been 33%, and the assumed FY 12 target would have been 67%, although the goal was only officially established this year with the FY 13 target. Because FDA is required to cover 100% of the firms every three years, the target for the first year of the new cycle, in this case FY 14, returns to 33%.

Human Drugs – Field Activities

Base Amount: $140,011,000 (BA: $129,993,000 / UF: $10,018,000)

To support the Human Drugs Program, ORA Field offices:

- Advise FDA leadership on enforcement, import, inspection, and laboratory policies,
- Assess industry compliance with applicable regulations to protect the public health,
- Conduct risk-based domestic and foreign premarket and postmarket inspections of drug manufacturers to assess their compliance with GMPs,
- Perform laboratory analyses to support inspections and verify compliance,
- Oversee the regulated products on a surveillance or “for cause” basis,
- Respond to emergencies and investigating incidents of product tampering and natural or intentional disasters that may affect FDA-regulated goods, and
- Develop criminal cases to address the marketing of counterfeit products through OCI and the Forensic Chemistry Center (FCC).

ORA executes its Human Drugs Program regulatory responsibilities in four subprogram areas:

- New Drug Review
  Base Amount: $35,684,000 (BA: $25,666,000 / UF: $10,018,000)
- Generic Drug Review
  Base Amount: $8,029,000 (BA: $8,029,000 / UF: $0)
- Drug Quality
  Base Amount: $91,884,000 (BA: $91,884,000 / UF: $0)
- Post Market Safety Oversight
  Base Amount: $4,414,000 (BA: $4,414,000 / UF: $0)

Detailed information on subprogram-specific activities appear in the Human Drugs tab in this budget that displays the FDA Human Drugs Program narrative.

Public Health Focus

ORA's public health focus addresses multiple program areas such as New Drug Review, Generic Drug Review, Drug Quality, and Post Market Safety Oversight within the Human Drugs Program.

ORA performs New and Generic Drug reviews and conducts inspections. The reviews assess the methods and facilities used to ensure strength, quality, and purity. The establishment inspections verify their ability to manufacture the product to the specifications stated in the application. ORA builds enforcement cases using a number of enforcement tools such as seizures, injunctions, and prosecutions. ORA is also responsible for the oversight and monitoring of drug industry recalls.

ORA conducts Bioresearch Monitoring program inspections to ensure the integrity of clinical data on which product approvals are based and, for investigations involving human subjects, to help protect the rights, safety, and welfare of these subjects.

Consumers' risk of exposure to defective drug products is minimized by conducting inspections, monitoring imports, and collecting, and analyzing product samples of domestic and foreign drug manufacturers. These activities prevent the marketing and assist in removing violative drug products from the market. Early detection of contaminated or defective human drug products and their ingredients continues to be a priority within ORA.

ORA's public health focus regarding post market safety oversight is to reduce adverse events such as injuries and deaths associated with unsafe, illegal, fraudulent, substandard, or improperly used products. ORA's inspection activities include inspections of Adverse Event Reporting and Risk Evaluation Mitigation Strategies (REMS). The REMS inspection is an evaluation of compliance with the risk evaluation plan that the FDA Amendments Act mandated.

Public Health Outcome

In an effort to increase public awareness and knowledge, and achieve beneficial public health outcomes from NDA reviews, FDA shares a series of lists on its website containing information on clinical investigators who have:

- Received notification from FDA of the intent to initiate administrative proceedings to determine if the person should be disqualified from receiving investigational products,
- Been disqualified or 'totally restricted' and are no longer eligible to receive investigational drugs, biologics, or devices,
- Been recommended for disqualification,
- Agreed to certain restrictions,
- Agreed to restrictions that have been subsequently removed, and
- Provided FDA with adequate assurances of their future compliance with requirements applicable to the use of investigational drugs and biologics.

Additionally, FDA provides a separate list of firms or persons who have been debarred under Section 306 of the FFCDA.

While FDA is actively engaged in regulating industry, FDA is working with industry to prevent drug shortage situations from arising from a variety of causes such as the unavailability of active ingredients or the failure to comply with current good manufacturing practices. To support FDA's ongoing efforts to prevent and resolve prescription drug shortages, ORA developed and issued a specific Import Bulletin to field offices, outlining enforcement discretion of specific product and manufacturer combinations to help prevent or alleviate potential drug shortage issues. This Import Bulletin was issued during FY 2012, and updated 12 times to reflect new product and manufacturer combinations, or to update existing product and manufacturer combinations.

In FY 2012, ORA expanded its drug testing capabilities to include antimicrobial effectiveness testing methodology in three separate ORA field laboratories. The data provided by ORA imparts new and important information needed in the evaluation and Center determination of product stability.

In FY 2012, ORA conducted 410 Good Clinical Practice inspections of CDER regulated establishments. Eighteen inspections resulted in findings of serious violations of FDA regulations. One establishment was cited for failure to maintain accurate case histories with respect to observations and data pertinent to the study. Another establishment was cited for having enrolled subjects who did not meet inclusion and exclusion criteria, obtaining informed consent from a subject using an informed consent form from a different study and inadequate case history records.
ORA also conducts inspections of Institutional Review Boards (IRBs). These types of inspections are intended to verify compliance with applicable FDA IRB regulations. In FY 2012, ORA conducted 100 IRB inspections of CDER regulated establishments. Seven

inspections resulted in serious violations of FDA regulations. Establishments were cited for violations including IRB approval of the conduct of research, but not ensuring that informed consent would be sought from each prospective subject or the subject's legally authorized representative.

In addition, ORA conducts inspections of non-clinical laboratories (Good Laboratory Practices or GLP). In FY 2012, the Office of Regulatory Affairs conducted 34 GLP inspections of CDER regulated establishments.

ORA supports the generic drug review program area and achieves positive public outcomes through pre-approval and post-approval inspections to verify application data and assess the firm's ability to manufacture products in accordance with GMPs. ORA also conducts inspections of bioequivalence studies to substantiate source data and verify accuracy, completeness, and regulatory compliance.

In FY 2012, ORA collaborated with CDER to develop a priority listing of Abbreviated New Drug Applications inspections, aiding in targeting inspectional resources, and creating Agency efficiencies by identifying generic drug manufacturing facilities for inspection to coincide with Center reviews of applications.

ORA field laboratories conducted enhanced drug surveillance activities during FY 2012. More than 150 products were tested as part of the program. Active Pharmaceutical Compounds intended for pharmacy compounding, identified as at-risk for economic adulteration, were targeted for analysis. Drug surveillance activities involving microbiological screening for drug products considered at risk for microbiological contamination were also implemented.

ORA is in the second of a three-year Cooperative Research & Development Agreement (CRADA) with the U.S. Pharmacopeia (USP) to participate in certification of USP reference standards, USP monograph modernization, and activities relating to economically motivated adulteration (EMA). These initiatives promote drug quality and efficacy that are vital in promoting public health. To date, ORA has completed more than 40 reference standard certifications and participated in updating three USP monographs.

ORA continues to collaborate with CDER in a Pharmacy Compounding Validation program to identify the most commonly compounded medications and develop and validate unofficial standardized testing methods. As of August 1, 2012, ORA had validated testing methods for ten commonly compounded drug products. The program ensures specialized drug products are analyzed appropriately to ensure quality, consistency, and efficacy for pharmacy compounded products.

The foreign drug inspection program continues to emphasize more surveillance driven foreign inspections as opposed to application driven foreign inspections. A total of 813 foreign drug inspections covering 62 different countries were conducted in FY 2012, exceeding the total completed in FY 2011 by 86 inspections. The dedicated foreign drug

cadre completed 212 or 26 percent of these inspections, while the global offices in India and China were responsible for 59 or seven percent of these inspections. This experienced group of investigators had significant outcomes. Of the 28 GMP based foreign warning letters issued by CDER in FY 2012, 13 or 46 percent have been issued from inspections conducted by either the dedicated foreign drug cadre or global offices. An example of one of the specific FY 2012 warning letters that led to positive public health outcomes is as follows:

- A warning letter was issued to an active ingredient penicillin manufacturer in Poland. The conditions noted during the inspection revealed that the manufacturer was not taking appropriate controls in order to minimize contamination in non-penicillin manufacturing areas. As a result of this inspection, the firm was added to a Detention Without Physical Examination (DWPE) Import Alert, thereby preventing unsafe products from entering the U.S. market.

ORA monitors recalls of human drugs that have been found to present safety concerns to assure that a firm's recall action is adequate to effectively remove the defective product from commerce. Through the classification process, the Center determines the level of public health risk the product presents. Appropriate public notification is also a component of FDA's recall program. In FY 2012, FDA classified and issued recall numbers for 28 Class I; 194 Class II; and 94 Class III recalls of human drug products.

In support of the President's Transparency Initiative, ORA started posting on the Internet the most common inspection observations of objectionable conditions or practices that are made during inspections. This information includes inspectional observation summaries from FY 2006 through FY 2012. Additionally, a searchable database of inspected facilities with FDA inspection classifications is posted that represents the final inspection classification for inspections conducted of clinical trial investigators, IRBs, and facilities that manufacture, process, pack, or hold an FDA-regulated product that is currently marketed.

During the first ten months of FY 2012, there have been two injunctions filed against drug firms and two seizures executed against drug products. These enforcement actions protect patient safety by assuring that manufacturers comply with laws and that violative products are not distributed into U.S. commerce.

During FY 2012, ORA's OCI made 249 drug related arrests, and secured 201 drug related convictions with fines, restitutions, and other monetary penalties in excess of $4.9 billion. Representative cases include:

Distribution of Adulterated and Misbranded Cancer Treatment Drugs – In June 2012, a person was convicted of distributing adulterated cancer drugs from overseas to a Missouri doctor and others. In May 2012, the Missouri doctor, who received the drugs, was likewise convicted after pleading guilty to one misdemeanor count of receiving misbranded prescription drugs, including cancer treatment drugs marketed in the United

States as Neupogen, Herceptin, and Rituxan. This doctor agreed to pay a civil settlement of over $1 million to resolve allegations that he submitted false claims to government health care programs for assorted misbranded cancer treatment drugs and agreed to be excluded from future participation in Federal health care programs for seven years. In February 2012, a third defendant pled guilty to one count of conspiracy to cause the introduction of adulterated prescription drugs into interstate commerce. This defendant was later sentenced to 24 months in prison and agreed to forfeit approximately $1.4 million dollars that was seized during the investigation.

Misbranded Drugs – Colchicine Toxicity Causes Death in Patients – In April 2012, a Texas compounding pharmacy and its owner pled guilty to two criminal violations of the FFDCA. The pleas were in conjunction with the compounding pharmacy's interstate shipment of two lots of colchicine injectable solution that led to the deaths of three people in the Pacific Northwest. At the time of production of the colchicine the pharmacy did not test their product for potency. FDA laboratory analysis of several vials of colchicine that were collected from the pharmacy showed some were super-potent and some were sub-potent making them misbranded because the actual levels of colchicine did not correspond with the levels listed on the vial labels.

OCI Proactive Ongoing Initiatives:

- **Operation Pangea** – Between September 25 and October 2, 2012, OCI participated in the fifth annual International Internet Week of Action, a global cooperative effort to combat the online sale and distribution of potentially counterfeit and illegal medical products. Dubbed "Operation Pangea V", OCI partnered with regulatory enforcement units from CDER, ORA's Division of Import Operations, and ORA's Office of Enforcement to identify and take action on more than 4,100 websites selling drug products in violation of U.S. law. In addition, warning letters were sent to Registries, Internet Service Providers (ISPs), and Domain Name Registrars (DNRs) informing them that these websites were selling products in violation of U.S. law.
- **Internet Investigations** – In April 2012, an OCI internet investigation, which relied on strong international law enforcement partnerships, resulted in the arrest and conviction of two Israeli citizens for selling counterfeit and misbranded drugs to U.S. citizens via the Internet. OCI agents identified more than 9,000 separate drug shipments to the United States that generated more than $1.4 million in gross proceeds.

ORA's post market safety oversight activities to reduce adverse events involves the review of manufacturers' adverse event and complaint files during inspections to determine if the firm is submitting all adverse drug event reports to FDA in accordance with regulatory time frames. ORA conducts follow-up inspections on adverse event reports when information from the manufacturer is needed to evaluate the risks involved. The final activity involves investigations of reported errors and product recalls so that program managers can collect information and develop error reduction strategies with manufacturers and the medical community in order to better protect the public health.

FDA continues to perform operations in response to the 2008 incident in which heparin contaminated with over-sulfated chondroitin sulfate was associated to a number of deaths in the United States. In FY 2012, ORA issued a new Import Alert to implement DWPE for those heparin suppliers implicated in the production of heparin contaminated with over-sulfated chondroitin sulfate, or for those manufacturing heparin outside of cGMPs. Currently, more than 30 firms are subject to DWPE under this import alert, which helps keep potentially contaminated product out of the United States.

In FY 2012, FDA worked with CBP's Laboratory Science Service when that agency detected passengers returning to the United States with elevated gamma radiation readings. Inspections were conducted identifying numerous current good manufacturing practice deficiencies and the potential breakthrough of detected isotopes from the columns used in producing these Positron Emission Tomography (PET) drugs. The inspection resulted in the firm recalling the drug product and removing the over-exposure potential from the public.

Performance Measures

The following table lists the performance measures associated with this program.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
224201: Number of foreign and domestic high-risk human drug inspections. *(Output)*	FY 2012: 805 Target: 750 (Target Exceeded)	750	750	Maintain

Biologics – Field Activities

Base Amount: $45,232,000 (BA: $40,513,000 / UF: $4,719,000)

The ORA Field Biologics Program supports the Biologics Program by:

- Assessing industry compliance with current good manufacturing practice and other applicable FDA regulations and recommending regulatory actions to CBER,
- Conducting risk-based inspections of domestic and foreign establishments to determine compliance with applicable requirements,
- Performing entry review of imported products,
- Assuring rights of human subjects participating in clinical trials are protected through proper oversight,
- Reviewing data submitted to FDA and used in support of applications to ensure it is valid and reliable,
- Monitoring recalls of violative products, and
- Investigating complaints.

ORA executes its Biologics Program regulatory responsibilities in three subprogram areas:

- Vaccines and Allergenic Products
  Base Amount: $5,842,000 (BA: $4,383,000 / UF: $1,459,000)
- Cells, Tissues and Gene Therapies
  Base Amount: $11,938,000 (BA: $10,756,000 / UF: $1,182,000)
- Blood and Blood Products
  Base Amount: $27,452,000 (BA: $25,374,000 / UF: $2,078,000)

Detailed information on subprogram-specific activities appear in the Biologics tab in this budget that displays the FDA Biologics Program narrative.

Public Health Focus

ORA supports the Biologics Program in ensuring the safety, purity, potency, and effectiveness of regulated products. ORA uses a number of enforcement tools to bring about industry compliance with the law. Injunctions stop or prevent future violations of the law, and Orders of Retention, Recall, or Destruction of biological products are used when manufacturing conditions do not provide adequate protections in accordance with regulations to prevent the risk of introduction, transmission, or spread of communicable disease.

Public Health Outcome

ORA accomplishes a majority of its regulatory and public health responsibilities by conducting inspections both domestically and abroad, by performing entry review on imported products, by investigating and building compliance cases, and by monitoring recalls.

Throughout FY 2012, ORA field investigators conducted surveillance inspections of biologic product manufacturers to assess manufacturing operations and document violations of current good manufacturing practice requirements. Efforts such as these continue to serve the American public health by ensuring that the industry continuously reviews the quality standards of their manufacturing operations to ensure the safety of biological products on the U.S. market. For example:

- In July 2012, ORA inspections of two foreign bacterial and viral vaccine manufacturers revealed corporate wide deviations from cGMPs resulting in the issuance of a Warning Letter to the manufacturer's corporate headquarters. During one of the inspections, ORA investigators with participation from CBER, found that the firm's re-validation of the sterility test method failed to detect yeast and mold that was

detected in the firm's aseptic processing area. The results of these inspections not only served to protect the health of the American public, but ensured corporate management addresses corrective actions to their manufacturing operations from a global perspective.

In FY 2012, ORA again exceeded both of the performance goals set for the Biologics Program:

- ORA conducted 1,073 blood bank inspections exceeding its goal of inspecting 1,000 of the highest risk registered blood bank and biological product manufacturers. While some of the inspections uncovered deviations from applicable cGMP regulations for blood and blood products that resulted in the issuance of warning letters but no product recalls, the majority of the inspections found the facilities to be operating in accordance with FDA requirements, thus ensuring the safety of their products.
- ORA accomplished 591 human tissue inspections surpassing the performance goal of 533 inspections. These inspections focused on the safe manufacture of man cells, Tissues and Cellular and Tissue-based Products (HCT/Ps) in accordance with the applicable regulations. HCT/Ps recovered from unknown or high risk donors could present a significant risk to human health as transmissible diseases may be present. These inspections assessed manufacturers of HCT/Ps including bone, skin, corneas, ligaments, tendons, and heart valves, among others.

In addition to regulatory efforts such as inspections to monitor the manufacturing of biological products, ORA pursues corrective actions as well. During FY 2012, OCI made seven biologic related arrests and secured eight biologic related convictions.

Representative cases include:

- In October 2011, a superseding indictment was handed down involving an individual who was conducting a clinical trial without FDA approval. This person obtained human placentas from at least one Las Vegas area hospital and surgically implanted tissue from the placenta(s) into at least 16 patients suffering from multiple sclerosis and other serious conditions. The defendants also made false representations to FDA regulatory investigators regarding their involvement in the scheme, conducted no meaningful follow-up with the patients who underwent the implant procedures, and concealed from patients and prospective patients the adverse effects suffered by previous patients. In November 2012, after a nearly four-week trial, two defendants from Nevada were each convicted of all charges.
- In December of 2011, three persons were charged with multiple mail fraud charges and the Introduction of a New Drug into Interstate Commerce as a result of their participation in a scheme to manufacture, distribute and sell to the public stem cells, and stem cell procedures that were not approved by FDA. According to the indictment, the defendants in this case manufactured, distributed, and used stems

cells produced from umbilical cord blood to perform procedures not approved by FDA to treat persons suffering from cancer, amyotrophic lateral sclerosis (ALS), multiple sclerosis (MS), and other autoimmune diseases. These types of efforts are given high priority as they serve to protect the most vulnerable of our population from products and treatments that are neither safe nor effective.

- In May of 2012, a defendant was convicted of distributing adulterated home test kits. The defendant owned and operated a company through which he sold the public test kits for sexually transmitted diseases, including kits to test for HIV and hepatitis. The test kits lacked pre-market FDA approval and had no FDA-granted investigational device exemption. Additionally, the defendant's website contained false statements about the company and the test kits and that the test kits were FDA registered devices. The impact of this case, and similar investigations conducted by OCI, is to reduce the number of unapproved and substandard testing kits, and thereby protect the public from the risks of false test results, particularly false negative readings that could cause a person not to seek appropriate medical treatment.
- In September 2012, two defendants were convicted in unrelated cases as a result of their participation in a scheme to manufacture, distribute, and sell to the public stem cells, and stem cell procedures that were not approved by FDA. These stem cell "therapies" were used to treat those suffering from cancer, ALS, MS, and other autoimmune diseases. The defendants falsely represented to patients that this treatment protocol had been reviewed by all levels of FDA and was an effective treatment for cure of the disease.

FDA's oversight helps to ensure that those in the public relying upon biological products are not exposed to potentially deadly diseases and otherwise dangerous biological products. Millions of patients receive these products each year and these inspections are conducted to ensure these products are not contaminated, do not become contaminated during manufacturing, and do not contain communicable disease agents. In addition to being used for treating many diseases, biological products are on the forefront of new treatment therapies available to patients where no therapies may have previously existed. Therefore these efforts are especially important as they serve to provide the most vulnerable of our population with treatments that are safe and effective.

Performance Measures

The following table lists the performance measures associated with this program.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
234202: Number of registered domestic blood bank and biologics manufacturing inspections. *(Output)*	FY 2012: 1,073 Target: 1,000 (Target Exceeded)	1,000	1,000	Maintain
234203: Number of human foreign and domestic tissue establishment inspections. *(Output)*	FY 2012: 591 Target: 533 (Target Exceeded)	533	570	+37

Animal Drugs and Feeds – Field Activities
Base Amount: $56,869,000 (BA: $53,205,000 / UF: $3,664,000)

ORA field offices support the Animal Drugs and Feed Program by assessing industry compliance with the applicable regulations to protect the public health. ORA achieves this assessment by conducting pre-market and post-market risk-based inspections of domestic and foreign establishments to determine the safety of manufactured products. ORA monitors and samples imports to ensure the safety of animal drugs and food defense related security of the feed supply and compliance with recalls of violative products. ORA collaborates with State, local, tribal, and territory counterparts to further FDA's food safety mission by funding contracts with State regulatory agencies to conduct inspections, collect and conduct sample analysis on regulated animal drug and feed products, and support the capacity building of State, local, tribal, and territory regulatory counterparts.

In instances of criminal activity, OCI complements the enforcement activities of the regular Field force. The Field Animal Drugs and Feeds Program is funded by appropriated dollars and user fee revenues from Animal Drug User Fee Act (ADUFA) and Animal Generic Drug User Fee Act (AGDUFA).

The Field Animal Drugs and Feeds Program executes its public health responsibilities in two major areas: food safety and medical product safety. Food safety focuses on four strategic areas to ensure the safety of the animal food and feed supply:

- Prioritizing Prevention
  Base Amount: $12,288,000 (BA: $12,288,000 / UF: $0)
- Strengthening Surveillance
  Base Amount: $13,657,000 (BA: $13,657,000 / UF: $0)
- Strengthening Enforcement
  Base Amount: $15,787,000 (BA: $12,598,000 / UF: $3,189,000)
- Improving Response and Recovery
  Base Amount: $9,851,000 (BA: $9,851,000 / UF: $0)

Pre- and post-market safety and compliance for companion animals and exotic animals that can transmit disease from animals to humans focuses on:

- Animal Drug Review
  Base Amount: $2,600,000 (BA: $2,125,000 / UF: $475,000)
- Post-market Safety and Compliance
  Base Amount: $2,686,000 (BA: $2,686,000 / UF: $0)

Detailed information on subprograms appear in the Animal Drugs and Feed tab in this budget that displays the FDA Animal Drugs and Feed Program narrative.

Public Health Focus

ORA focuses on prevention through outreach coordination and technical assistance. In addition, internal and external training is a top Field priority to gain expertise and encourage collaboration with external stakeholders.

To strengthen bio-security, surveillance, and risk analysis, ORA conducts import prior notice and entry reviews, import field examinations, sample collections, and laboratory analyses.

Laboratory activities include sample analysis, method validation, and methods development to enable FDA to develop solutions for specific regulatory problems. ORA applies risk based principles to the life cycle of ORA scientific operations – including sample collection, sample analysis, data reporting, and data analysis.

ORA inspectional activities that support the Animal Drugs and Feeds Program include conducting pre- and post-market inspections of domestic and foreign animal drug and feed establishments to determine the safety and effectiveness of manufactured products and conducts Bovine Spongiform Encephalopathy (BSE) inspections to prevent the establishment and amplification of BSE through feed in the United States. ORA also conducts follow-up investigations on reports of tissue residues to ensure a safe human food supply by reducing the incidents of antibiotic residues in the food supply.

With the integrated food supply chain, it is more important than ever for ORA to work with its regulatory partners, specifically its Federal, State, local, tribal, and territorial partners, in order to protect the nation's food supply.

FDA Food Safety Strategy

The FDA FVM Strategic Plan 2012 – 2016 can be found at the following FDA web link: http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofFoods/UCM273732.pdf

ORA achieves the overall FDA strategy by focusing on preventing food safety problems from occurring rather than on reacting to problems after they occur. Implementing the provisions of FSMA is completed through the development of regulations, standards, and guidance documents. These activities include the adoption of science-based regulations that protect the food and feed supply from contamination, including the identification of the most significant foodborne contaminants and an evaluation of the effectiveness of existing controls for those contaminants.

ORA achieves these goals by implementing risk-based systems, which includes enhancing risk-based decision making, developing metrics and goals for risk-based food and feed safety and a model for evidence-based resource planning, setting priorities, maintaining and strengthening mission-critical science capabilities, administering

centralized planning and performance measurement, and sharing information internally and externally.

ORA implements new enforcement authorities designed to achieve higher rates of compliance with prevention-based and risk-based food and feed safety standards, conducts risk-based domestic and foreign food safety inspections, implements new enforcement tools such as mandatory recall authority, and improves the collaboration with State, local, tribal, and territorial officials and staff on inspection and compliance efforts. By adopting risk-based approaches to conducting inspections, ORA is able to more efficiently utilize scarce resources and maximize the public health benefit to consumers by ensuring high rates of compliance and assuring that imported food and feed meet preventive controls standards.

Public Health Outcome

In FY 2012, import field investigators have performed more than 7,000 field and label examinations on entry lines of animal drugs and feeds. These activities are performed to identify violations, for example to verify that the product matches the information transmitted electronically and that the product labeling meets applicable compliance requirements.

While performing an examination of a foreign manufactured dietary supplement for pet use offered for import into the United States. ORA investigators determined that the product lacked an approved new animal drug application. ORA refused the entry and took regulatory action to ensure the shipment was not distributed in the United States. These activities continue to assure that unapproved products are not distributed in U.S. commerce and are re-exported or destroyed as required under the FFDCA.

During FY 2012, ORA issued seven notices identifying modifications to Import Alerts encompassing numerous animal drugs and feed manufacturers and products. These actions resulted from ORA import surveillance collections and testing of regulated drug products when they were offered for import into the United States, and “for cause” sampling of imported products based on findings of violations during inspections of foreign manufacturers. These notices provide increased coverage at the border to assure these products are not available to the U.S. consumer.

ORA leverages outreach opportunities to raise awareness and understanding of current policies and guidance as well as provide insight and information related to pending and new requirements. In FY 2012, ORA participated in more than 50 outreach events including the National Customs Brokers and Forwarders Association of America, Inc. 38th annual conference. ORA provided updates related to import initiatives; most notably, updates related to the status of FDA’s efforts to implement the import related sections of FSMA.

ORA outreach efforts also included participation in a variety of public outreach activities attended by regulated industry, other government agencies, and foreign regulatory bodies. In FY 2012, ORA awarded 35 contracts to States under the Feed Safety BSE contract program. These contracts assist FDA in establishing an expanded level of inspection coverage as well as surveillance and education, greatly enhancing regulatory oversight.

In FY 2012, ORA collected milk samples as part of an on-going assignment. The assignment calls for the collection of more than 1,800 milk samples to be analyzed for the presence of drug residues. ORA laboratories developed and validated two multi-residue screening methods that analyze a total of 31 drug residues in each milk sample. The results of the assignment will provide FDA with the information it needs to determine whether dairy farms with histories of drug residue violations in meat from culled adult dairy cattle may also have unacceptable drug residues in milk. FDA will work with industry to develop an action plan to address any potential public health issues.

ORA collected 79 poultry feed as an extension of an on-going *Salmonella* assignment and analyzed these in the ORA laboratories. If the samples contained certain *Salmonella* serotypes that could be harmful to poultry, these were deemed to be unacceptable for feeding to chickens.

ORA uses a combination of techniques to perform import surveillance including electronic information technology for risk-based entry screening, intensive ORA staff surveillance, physical exams, and laboratory analysis.

Because the number and complexity of FDA-regulated imported products is increasing exponentially, ORA increased its efforts to strengthen surveillance and risk analysis. ORA issued seven notices identifying modifications to animal drugs and feed related Import Alerts, conducted routine and targeted surveillance examinations, sampling, and established a committee in collaboration with the Association of American Feed Control Officials consisting of State and FDA officials to develop Animal Feed Regulatory Program Standards (AFRPS).

In FY 2012, ORA, in collaboration with CBP, conducted examinations of imported food and feed shipments to identify shipments that contain smuggled animal feed products. ORA and CBP have conducted more than 1,100 examinations and taken action against several entries that contained smuggled products. Smuggled animal feed products pose significant concern to ORA because they have not been examined to determine compliance with FDA regulations.

In FY 2012, ORA awarded contracts and grants to the States to increase collaborative efforts, leverage existing resources and bolstering an integrated feed safety system. These contracts and grants included:

- Tissue residue program contracts to States to provide for completion of tissue residue inspections by State inspectors,
- Food Protection Task Force grants to State and local groups,
- Small Scientific Conference grants to associations to increase interactions to assure uniformity and consistency in enforcement activities, and
- Contracts and cooperative agreements awarded to States under the Feed Safety BSE program.

In FY 2012 ORA provided funding to State, local, tribal, and territorial partners to support capacity building in the areas of recalls and inspections in support of Section 210 of FSMA. Several feed programs received funding under these cooperative agreements to build their capacity, capabilities, and infrastructure in these critical areas.

ORA collaborated with the Center for Veterinary Medicine (CVM) and the Association of American Feed Control Officials to develop AFRPS. These standards are currently in review and, when issued, will provide uniformity and consistency among regulatory programs responsible for the inspection of feed facilities across the Nation. These standards are a critical component of an integrated food safety system as envisioned by FSMA.

Currently, the best approach to improving the safety and security of feed is to utilize resources to expand targeting and follow through in potentially high-risk areas such as:

- Reviewing risk-based scenarios of bioterrorism and developing criteria that target animal feed and feed ingredients that are at risk for intentional contamination,
- Working in conjunction with CVM to take steps to reinstate the milk monitoring program including developing methods,
- Creating and launching a searchable FDA webpage and database for recalls to including a process and tracking system,
- Implementing a new streamlined enforcement process for seizures and injunctions,
- Issuing 76 warning letters to prevent the continued distribution of adulterated animal products in U.S. commerce,
- Drafting a new Compliance Policy Guide describing policy for refusing imports of foods and medical products exported from facilities that have refused an FDA inspection, and
- Supporting the development of State infrastructure, territorial and tribal animal feed safety, and BSE prevention programs to assure a broader regulatory framework for the U.S. feed supply.

When firms are found to be operating in violation of FDA requirements, FDA takes regulatory action to ensure firms are in compliance while ensuring that products of concern do not reach U.S. consumers. When firms refuse to comply with FDA regulations, FDA takes further action to ensure unsafe products do not reach U.S.

consumers and works to request these firms potentially shut down their operations. In January 2012, ORA issued notices of shutdown and liquidated damages against two dairy farms for violating requirements of consent decrees they had entered into with FDA. Neither location had implemented appropriate corrective actions to ensure they were operating in accordance with FDA regulations; however both farms continued to operate.

ORA initiated an investigation into the manufacturing and marketing of two Type B medicated animal feeds used for show cattle in March 2012. The products posed a human safety concern when not handled in an appropriate manner; however, the products did not have a warning statement regarding human handling. Additional concerns existed given that show animals have a higher rate of handling by younger people. The investigation identified the manufacturers of the products and also uncovered that the products were manufactured at an unlicensed feed mill. ORA's investigation led to a recall of all feed lots manufactured in a two year time frame.

When a product is found to be adulterated, misbranded, or otherwise out of compliance, it may be subject to refusal. A refused product must be exported or destroyed. In FY 2012, ORA refused more than 25,000 lines of FDA regulated product of which more than 350 lines were of animal feed and drug products.

Submission of accurate prior notice data for imported animal food and feed shipments ensures that ORA can complete meaningful bio-security risk assessments. In FY 2012, ORA made more than 400 informed compliance calls to regulated trade due to incomplete or inaccurate prior notice data submissions. ORA initiated more than 700 compliance enforcement cases, in conjunction with CBP, where Bioterrorism Preparedness and Response Act of 2002 registration information was lacking and the inadequate prior notice data was so egregious that it restricted ORA's ability to perform meaningful risk assessments. These actions require resubmission of accurate prior notice data before the imported food and feed shipments are allowed to enter the United States.

During FY 2012, there were four injunctions against farms that had offered for sale animals for slaughter found to be adulterated with drug residues. These actions protect consumers from exposure to these meats and require farms to meet these statutory and regulatory requirements.

During FY 2012, FDA classified 28 Class I; 26 Class II; and 13 Class III recalls of animal products regulated by FDA. These included recalls of pet food, animal feed, animal drugs, and animal devices.

In April 2012, the U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) confirmed a case of BSE in a dairy cow. FDA immediately began working with APHIS, the State, and the CDC to investigate the incident. ORA performed inspections at more than ten feed manufacture facilities and dairy farms who had handled the animal during its life. The ORA inspections determined that no

deviances from FDA regulations had occurred in the products of the feed that would have led to the positive BSE finding. Additionally, further analysis of the animals tissue by USDA determined that the form of BSE found in the animal was spontaneously forming and not related to food or feed practices. The quick and collaborative response of the State and Federal agencies involved led to an expedited resolution of the incident. U.S. and global consumers were also reassured that domestic cattle and their by-products for human and animal consumption were safe for consumption.

In FY 2012, ORA responded to numerous incidents reported through the Safety Reporting Portal (SRP) regarding pet foods and animal feed. In November 2011, FDA began receiving numerous reports through the SRP indicating adverse health events in dogs. The submissions had a commonality of pets having consuming foreign-manufactured chicken jerky pet treats. ORA implemented an import sampling and analysis bulletin (Import Bulletin 72-B04) to allow for testing to identify potential causes of the adverse reactions. ORA investigators collected more than 50 samples which were analyzed for a variety of potential contaminants including melamine/cyanuric acid, ethylene glycol, diethylene glycol, and propylene glycol. ORA developed improved methodologies to identify procedures to enhance the recovery and detection of the targeted contaminants. Additionally, ORA expedited the inspection of five foreign manufacturing facilities of suspect pet treats. ORA conducted the inspections with our foreign regulatory counterparts, which led to a second tier of inspections of foreign-sourced ingredient suppliers. FDA continues to investigate this issue and has established a scientific working group to evaluate possible contaminant sources. As a result of ORA's import sampling bulletin, propylene glycol was detected in cat treats, a violation of FDA requirements. These findings led to the establishment of a new Import Alert to ensure no future shipments of products of concern gain entry into the U.S. market without assurance that they are in compliance with FDA regulations and safe for animal consumption.

ORA leverages its regulatory partnerships to rapidly respond to outbreaks and facility recovery. Examples of these partnerships include:

- State contracts,
- FERN laboratories,
- Rapid response cooperative agreements,
- Food Protection Task Force grants,
- BSE contracts and cooperative agreements, and
- 50-State Meetings.

In FY 2012, ORA funded the expansion of the RRT cooperative agreement with the inclusion of new States into the program in support of continued and widespread development of an all hazards response network for food and feed emergencies.

ORA's Field force conducts preapproval inspections to support CVM's review of premarket applications for pioneer and generic animal drugs. The Field inspects

manufacturing establishments to determine their ability to manufacture the product to the specifications stated in their application. ORA performs inspections of non-clinical laboratories engaged in the collection of data to determine whether Good Laboratory Practices are followed. Accurate data is essential to the review and approval of new animal drugs. Inspections also ensure that the rights and welfare of animals are protected.

ORA performs routine inspections of regulated industry to ensure compliance with FDA regulations. In FY 2012, ORA conducted more than 55 animal drug inspections in 14 different countries

ORA monitors and samples imports to ensure the safety of the animal drug supply. In instances of criminal activity, OCI and the FCC complement the regular Field force activities.

ORA supports the CVM's evaluation of adverse event reports. The Field offices conduct follow-up inspections on adverse event reports when information from the manufacturer is needed to evaluate the risks involved. In addition, ORA reviews adverse event and complaint files during inspections for compliance with FDA reporting regulations. In the event of a public health incident concerning a disease from an animal, for example *Salmonella* from pet turtles, ORA assists CVM by conducting appropriate investigations. Targeted inspections allow for efficient use of FDA resources while focusing efforts on products of concern that are destined for or may already be in the U.S. market.

During FY 2012, OCI made six Animal Drugs related arrests and secured two convictions with fines.

One such investigation concerned the introduction of unapproved animal drugs. In July 2012, an internet company pled guilty to distributing unapproved animal medications throughout the United States. The canine medication was for heartworms and was not approved by FDA for use. This large internet distributor also imported various unapproved drugs that were advertised falsely for other medical conditions. The safety and supply of pet foods and products, like human foods, must be pure and wholesome and contain no harmful or deleterious substances and be truthfully labeled. OCI's investigations into illegal activities related to animal drugs and products prevent and protect animals from dangerous unapproved medical treatment.

Performance Measures

The following table lists the performance measures associated with this program.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
244202: Number of domestic and foreign high-risk animal	FY 2012: 271 Target: 250	250	250	Maintain

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
drug and feed inspections. *(Output)*	(Target Exceeded)			
244203: Number of targeted prohibited material BSE inspections. *(Output)*	FY 2012: 548 Target: 500 (Target Exceeded)	500	500	Maintain

Devices and Radiological Health – Field Activities
Base Amount: $95,334,000 (BA: $81,197,000 / UF: $14,137,000

ORA Field offices support Devices and Radiological Health Program activities by:

- Assessing industry compliance with applicable regulations,
- Conducting pre-market and post-market inspections of domestic and foreign manufacturers,
- Investigating medical device reports (MDR) and consumer complaints,
- Monitoring and evaluates compliance with recalls of violative products,
- Performing laboratory analysis to support inspections,
- Reviewing and evaluating imports of medical devices and radiological products to ensure products meet FDA quality standards, and
- Conducting enforcement activities.

ORA executes its Devices and Radiological Health program regulatory responsibilities in five subprogram areas:

- Premarket Device Review
  Base Amount: $8,465,000 (BA: $7,457,000 / UF: $1,008,000)
- Postmarket Safety
  Base Amount: $791,000 (BA: $739,000 / UF: $52,000)
- Compliance, Enforcement and Radiation Safety
  Base Amount: $68,474,000 (BA: $68,474,000 / UF: $0)
- Device Innovation and Regulatory Science
  Base Amount: $1,784,000 (BA: $1,784,000 / UF: $0)
- Mammography Quality Standards Act
  Base Amount: $15,820,000 (BA: $2,743,000 / UF: $13,077,000)

Detailed information on subprogram-specific activities appears in the Devices and Radiological Health tab in this budget that displays the FDA Devices and Radiological Health Program narrative.

Public Health Focus

The ORA Field force supports the Devices and Radiological Health Program in the initial phases of the total product life cycle by conducting pre-approval inspections of domestic and foreign establishments to determine if the facility is able to manufacture products according to the specifications stated in their application. ORA also conducts bioresearch monitoring inspections of clinical research studies – including the studies' clinical investigators, sponsors and monitors, and Institutional Review Boards – to safeguard patients and to validate laboratory methods for device premarket application decisions.

ORA provides support to post-market safety by conducting follow-up investigations and inspections of MDR reports at either the reporting medical facility or the manufacturer. These inspections are conducted to identify significant GMP problems by analyzing recurring manufacturing and product problems and by performing trend analyses. ORA collects data on complaints, significant problems, and potential hazards so that corrective actions can be initiated for hazardous products in the marketplace. ORA also conducts bioresearch monitoring inspections of post-approval studies, which monitor the post-market safety of products already available to the public for use.

The ORA Field force supports the program by advising FDA leadership on enforcement, import, inspection, and laboratory policies. Through its nationwide field offices and laboratories, ORA supports Compliance, Enforcement, and Radiation Safety activities by conducting risk-based domestic and foreign post-market inspections, field examinations, and sampling of medical device manufacturers to assess compliance with the Quality Systems regulations. This includes conducting inspections of reprocessors of single-use devices and manufacturers of radiation emitting products.

Radiological health activities include methods development and analyses of radiation emitting products such as lasers, sunlamps, and x-ray equipment to ensure that they comply with applicable performance standards. In addition to overseeing the regulated products on a surveillance or for cause basis, ORA responds to emergencies and investigates incidents of product tampering and natural or intentional disasters that may affect FDA-regulated products.

In order to address rapidly expanding technologies in devices and other product areas and to enhance current collaborative endeavors within and outside FDA, ORA continues to develop partnerships aimed to advance regulatory science. The focused efforts of ORA's laboratories, in collaboration with academia, Federal and State partners, continue to ensure that suspect medical devices are removed from U.S. commerce.

Additionally to protect consumers and advance public health for women, ORA continues to focus resources on health prevention by carrying out the mammography facility inspection contract program with the States, which includes an annual audit of State inspectors and FDA-provided training for State inspectors.

Public Health Outcome

ORA conducts inspections to ensure that medical device establishments are able to manufacture products according to the specifications outlined in an application and that concerns or issues raised during review of the application are accounted for. ORA efforts help to assure that medical products are cleared or approved based on reliable data and evidence of manufacturing capability, and once manufactured, become a viable supply of safe commodities for U.S. consumers.

ORA collaborates with the Center for Devices and Radiological Health (CDRH) to ensure that ORA field staff conduct the most efficient medical device inspections possible. This collaboration provides ORA investigators with information on the use of the device being studied, previous clinical trials, and concerns raised during review of preapproval inspections. These activities allow FDA to efficiently focus its available inspection resources on significant issues related to data integrity and human subject protection.

ORA conducts inspections of both domestic and foreign medical device firms on a periodic basis for surveillance purposes and on a for-cause basis when issues or concerns have been identified. These inspections help to ensure the marketplace is safe from defective or hazardous products.

In FY 2012, FDA conducted 453 foreign inspections of Medical Device and Radiological Health facilities in 35 countries. The dedicated foreign device cadre conducted approximately 166 inspections. In follow-up to objectionable conditions noted during these inspections, FDA issued 48 Warning Letters, ten of which included placing the firm on Import alert with automatic detention. Specific examples of the dedicated device cadre accomplishments include:

- In April 2012, an ORA device cadre inspection revealed that a foreign manufacturer of cardiovascular devices failed to comply with cGMP requirements relating to the manufacture of blood pressure and electrocardiographic monitoring systems. As a result of the inspection, FDA issued a Warning Letter to the firm and these devices were placed on detention without physical examination preventing them from entering the U.S. market.
- In May 2012, an ORA device cadre inspection of a foreign manufacturer of sterile syringes revealed several cGMP deficiencies. The firm was issued a Warning Letter and the devices were prevented from entering the U.S. Market.

During FY 2012, FDA classified and issued recall numbers for 57 Class I (highest risk); 1,043 Class II (lower risk); and 90 Class III (lowest risk) recalls of medical device products. Also in FY 2012, ORA issued 127 notices identifying modifications to medical device-related Import Alerts encompassing numerous medical device products and medical device firms determined to be manufacturing or shipping violative medical device

products. These actions were a result of ORA import surveillance collections, and testing of regulated products at the time they were offered for import into the United States, as well as for cause sampling of imported products based on ORA findings of violations during inspections of foreign manufacturers. These notices serve to provide increased coverage at the border to assure these products are not available to the U.S. consumer.

In FY 2012, OCI made 16 device related arrests and secured 18 device related conviction. Four representative cases include:

In FY 2012, ORA inspected the manufacturer of a gel product, used during endoscopy procedures and implicated in bacterial infections at a hospital. Samples collected from the inspection were analyzed by ORA Scientists and were found to be contaminated with multiple organisms. The inspection findings led to multiple lots of the products being recalled by the firm. ORA's activities ensured that products of concern were removed from the market and not a threat to U.S. patients.

In May of 2012, a Criminal Information was filed charging the defendant with introducing adulterated medical devices into interstate commerce in violation of the Federal Food, Drug, and Cosmetic (FD&C) Act. According to the charges in the Information, the defendant acted with the intent to defraud and mislead FDA with regard to the manufacturing procedures that were in place for an electro-surgical device used to cauterize tissue. This case characterizes the need for medical devices manufacturers to comply in accordance with GMPs as set forth in the FD&C Act.

In July of 2012, a defendant was sentenced for conspiring to introduce and deliver into interstate commerce an adulterated and misbranded device. The subject defendant and others endangered customers' lives by injecting them with commercial silicone, causing at least one victim to suffer lung damage from a substance not approved by FDA. A second defendant was later scheduled to be sentenced for conspiracy. This investigation and other cases involving adulterated and unapproved products is essential for preventing and protecting the public from dangerous products not approved for medical and cosmetic use by FDA.

In August 2012, ORA worked to increase surveillance of contact lens shipments to ensure importations of these products met applicable requirements. More than 4,700 lines of contact lenses were imported during the increased surveillance period. ORA identified a number of firms for further follow up and continues to work to subject these non-compliant products to detention without physical examination. To ensure these efforts are maintained, OCI and Division of Import Operations in conjunction with several other regulatory and investigative agencies initiated Operation Double Vision. This operation intends to continue targeting the illegal importation, distribution and sales of counterfeit, misbranded or adulterated contact lenses, which are violations of the FD&C Act. These actions serve to keep these potentially debilitating devices out of the U.S. marketplace.

Additionally in FY 2012, ORA worked with CDRH to execute a pilot program designed to increase the review efficiency of inspectional findings related to pre-clearance 510(k) violations. This pilot encourages early collaboration between the field and center to quickly determine whether regulatory action is required to correct deficiencies observed during inspections. The expected outcome of the pilot is speedier review of inspectional findings and an efficient issuance of Warning Letters, if appropriate. As the pilot continues, ORA and CDRH are assessing the results, have made enhancements to internal communications, and have made efficiencies in compliance timeframes. The result of rapid decision-making and communication with manufacturers is swifter compliance action by industry and improved public health protection.

The ORA Field force supports the Mammography Quality Standards Act (MQSA) program by managing State-conducted inspections annually and by conducting foreign inspections to ensure the safety of mammography conducted in military facilities located in foreign countries. To ensure high quality facility inspections conducted by the States, ORA coordinated with CDRH to offer annual MQSA training courses to new State inspectors as well as to provide continuing education for certified State inspectors. FDA also added free online training in FY 2012 to ensure FDA and State MQSA inspectors are able to maintain their required continued education units if training funds are limited. Maintaining the contract program through collaboration with qualified State partners maximizes resources dedicated to MQSA and ensures that a greater number of mammography facilities are inspected each year than could be accomplished by an individual program alone.

ORA's Winchester Engineering and Analytical Center (WEAC) conducts analyses and develops new analytical test methods for medical devices and radiation emitting electronic products in support of regulatory actions to ensure safe and effective medical devices.

ORA's medical device laboratory analyses utilize a risk-based approach focusing on device categories that have historically been responsible for a number of adverse events and recalls. The focused efforts of ORA's laboratories, in collaboration with academia, Federal and State partners, continue to ensure that suspect medical devices are removed from U.S. commerce. ORA scientists' analyses also provide support for OCI and U.S. attorneys to build investigations as well as those of other partners.

Performance Measures

The following table lists the performance measures associated with this program.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
253201: Number of Medical Device Bioresearch Monitoring (BIMO) inspections. *(Output)*	FY 2012: 305 Target: 300 (Target Exceeded)	300	300	Maintain
254201: Number of domestic and foreign Class II and Class III device inspections. *(Output)*	FY 2012: 1,927 Target: 1,515 (Target Exceeded)	1,515	1,600	+85

Tobacco – Field Activities

Base Amount: $6,250,000 (All UF)

ORA Field offices support Tobacco Control Act Program activities by:

- Collecting and analyzing samples of tobacco products to ensure compliance with the requirements of the Tobacco Control Act and other applicable regulations,
- Providing training to ORA field employees and assisting in the development of training materials for employees working under FDA contracts with U.S. States and territories to conduct tobacco retail inspections on behalf of FDA, and
- Conducting investigations and inspections to assess compliance with the requirements of the Tobacco Control Act and other applicable regulations.

ORA executes its Tobacco Control Act program regulatory responsibilities under only one of the three subprogram areas:

- Reducing Youth Initiation to Tobacco
  Base Amount: $6,250,000 (UF: $6,250,000)

Detailed information on the subprogram-specific activities appear in the Tobacco tab in this budget that displays the FDA Tobacco Control Act Program narrative.

Public Health Focus

To ensure compliance with the Tobacco Control Act, FDA conducts surveillance, investigations, inspections, sample collections, and detention/refusal of tobacco products.

ORA has established and continues to maintain a testing laboratory at the Southeast Regional Laboratory (SRL) with expertise and capacity to analyze tobacco products. The ORA SRL laboratory has been acquiring specific testing equipment such as mass spectrometers and smoke machines, and continues to work towards developing multi-residue flavor methods to detect unpermitted compounds that impart a characterizing

flavor to tobacco products. In addition, SRL, in conjunction with ORA headquarters, has been collaborating with other federal laboratory partners to leverage information, intelligence, and experience. Also of note, ORA's FCC laboratory will provide support to OCI to identify criminal violations in tobacco-product related cases.

In FY 2012, ORA continued to perform inspections of registered tobacco product establishments to determine their compliance with the laws and regulations enforced by FDA. During these inspections, ORA determines compliance with the provisions of the law including registration, product and ingredient listing, packaging, labeling, and advertising requirements, and marketing authorization for new or modified risk tobacco products.

Public Health Outcome

ORA carries out a multi-tiered approach towards enforcing the requirements of the Tobacco Control Act. In addition to inspecting registered tobacco establishments, ORA conducts investigations at sports and entertainment events to ensure tobacco manufacturers promote and distribute their products in accordance with the law. These inspections and investigations help to ensure that the regulated tobacco industry complies with the tobacco provisions of the FD&C Act and its implementing regulations.

Furthermore, working with the Center for Tobacco Products (CTP), ORA issued two import alerts related to the restrictions on the terms "low," "mild," and "light" to describe tobacco products and for prohibited candy or fruit flavored cigarettes to identify, detain, and refuse these products being offered for import. This effort establishes a mechanism for detention without physical examination of imported tobacco products found to be adulterated or which otherwise do not conform to the same regulatory requirements as domestically-manufactured tobacco products.

Working collaboratively with CTP, ORA continues to expand its program to train investigators to perform tobacco manufacturer inspections, thus ensuring that the investigators are well-trained in tobacco product inspection techniques.

ORA's commissioning program allows the U.S. State and territorial agencies to perform tobacco retail inspections on FDA's behalf and share information related to these retail inspections. As of September 30 2012, officials have been commissioned in 37 States and the District of Columbia.

From October 1, 2011 through September 30, 2012, tobacco-commissioned officials have conducted more than 87,000 tobacco retail inspections.

On the analytical front, ORA has been working establishing tobacco flavors methods so that the ban on characterizing flavors under the Tobacco Control Act can be enforced through special testing assignments.

During FY 2012, OCI made 16 tobacco related arrests and secured one tobacco related conviction. Two representative cases include:

Foreign-based distributor of counterfeit tobacco products – In June of 2012, a Chinese national was indicted in Providence, R.I., for selling and importing counterfeit tobacco products into the U.S. from China. The subject has been detained since his arrest in Miami on June 4, 2012, by FDA/OCI. OCI agents, acting in an undercover capacity, arranged for the shipment from China to the United States of a 20-foot cargo container containing 17 pallets of alleged counterfeit Marlboro cigarettes, worth in excess of one million dollars.

Domestic-based distributor of counterfeit tobacco products – In July 2012, two individuals were arrested for the distribution of counterfeit tobacco and pharmaceutical products in the Los Angeles, California area. During this multi-agency effort, OCI agents and other participating agencies and officers executed search warrants in east Los Angeles and the surrounding area resulting in the seizure of nearly $2,000,000 in counterfeit cigarettes and $100,000 in counterfeit Viagra pills.

Information Technology Investments – Field Activities (ORA) (Base Amount is included in the applicable Program Description and Accomplishments sections.)

ORA's IT systems support its field activities in accomplishing its mission by providing ORA the ability to plan and assign work, collect, store and analyze large volumes of regulatory, scientific, compliance and risk-based data resulting from this work, mine this data for trends and other useful information as well as to develop compliance and regulatory actions and support agency policies. ORA's IT systems are divided into three initiatives:

Mission Accomplishment and Regulatory Compliance Services (MARCS)
MARCS is the primary IT initiative for realizing the automation of all ORA work flows (other than laboratories) by reengineering and improving the functionality of ORA's underperforming legacy technologies as well as standardizing applications while searching for opportunities to improve ORA business processes. This effort will improve the efficiency of FDA Field Operations staff by:

- Reducing discrepancies in regulatory data by providing a unified end to end electronic work flow, resulting in reduced manual data entry, improved data validation and a reduction in the time needed to complete Field operations
- Improving the quality of regulatory data through a standardized data structure and improved, consistent user interface, resulting in accurate decision making, especially in regards to real time decisions during public health emergencies
- Improving the ability to track progress of work assignments from beginning to end by accurately cataloging operations, resulting in improved development and execution of the planned work, including improved targeting of high-risk products

- Enabling mobile technology that will allow for onsite, online and offline collection of data and entry of field operation results, thereby reducing the time required for the operations. This will result in greater inspection frequency, especially regarding high-risk foods
- Improving compliance targeting and analysis to better protect the public health and more quickly provide information to Congress, other Federal agencies, affected states as well as the public.

Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT)
FDA will continue to improve the processing of import data received through automated compliance targeting assessment algorithms using the screening tool. Use of PREDICT reduces staff time spent on low risk products and allows a greater focus on high-risk items offered for import.

Automated Laboratory Management (ALM)
Automated Laboratory Management (ALM) contains three components: Laboratory Information Management System (LIMS), Electronic Laboratory Exchange Network (eLEXNET), and the Quality Management Information System (QMiS).

- LIMS is being developed to provide a comprehensive management system for the ORA laboratories, eliminate many manual processes, reduce duplicate data entry, and increase surge capacity and throughput resulting in greater laboratory staff efficiency and an increased ability to respond to public health emergencies in a timely manner.
- eLEXNET is focused on protecting the Nation's food supply from terrorist activity and other threats. It provides a direct interface with Department of Homeland Security and the Food Emergency Response Network to provide a nationwide and highly skilled work force with access to data from hundreds of laboratories that can be called upon in a public health emergency. Current work on eLEXNET includes improvements to data sharing and collaboration.
- QMiS is dedicated to continuous quality improvement at ORA. QMiS supports the implementation of ORA quality procedures, including support for ORA laboratory accreditation. QMiS is continuing to roll out additional quality procedures.

Regulatory Business Information Services (RBIS)

Regulatory Business Information Services (RBIS) is responsible for providing ORA with an enterprise business intelligence solution where FDA regulatory and compliance data is centralized, cleansed, and integrated in a single repository for timely and effective reporting, analysis, planning, management, and decision support of all FDA Center and Field operations and activities. RBIS improves data quality relating to FDA regulated firms through name & address validation, standardization, matching, and survivorship to provide trusted data for reporting and analysis.

RBIS is comprised of the following systems:

- Online Reporting Analysis Decision Support System (ORADSS) integrates data from multiple centers and ORA repositories to present a single view of data for planning, reporting, analysis, and decision support. ORADSS is undergoing a redesign to better structure data and improve end user reporting and analysis that will result in the required data being available to the FDA Field users when needed and improving the users' ability to complete their work in a timely, efficient and effective manner.
- Firms Master List Services (FMLS) is a custom-built Master Data Management application that identifies and removes duplicate firms from ORA systems, integrates registered firms with ORA firms, and provides services to validate addresses and firms, thereby serving as an authoritative source for firm data. FMLS is strengthening its ability to validate firm data. The plan is to evaluate and implement new commercial off-the-shelf (COTS) solutions to help manage more complex business rules, resulting in improved integrity, validity, accuracy, efficiency, utility, and quality throughout all of the ORA Field operations.
- Online Program Analysis System captures monthly data on ORA field accomplishments information, for reporting and multi-dimensional historical and trend analysis in support of ORA's planning, evaluation and management activities.

Funding History Table with FTE Totals

The following table displays funding and full time equivalent (FTE) staffing levels from FY 2010 through FY 2013, plus FY 2014 request.

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
FY 2010 Actual	$869,112,000	$847,000,000	$22,112,000	4,235
FY 2011 Actual	$912,120,000	$890,474,000	$21,646,000	4,570
FY 2012 Actual	$931,778,000	$906,768,000	$25,010,000	4,451
FY 2013 CR	$1,019,992,000	$911,279,000	$108,713,000	4,769
FY 2014 Request	$1,217,008,000	$917,329,000	$299,679,000	5,255

Summary of the Budget Request

The FY 2014 budget request for ORA is $1,217,008,000 supporting 5,255 FTE. This amount is an increase of $256,263,000 above the FY 2012 Enacted Level.

The base funding for ORA is $960,745,000. Base funding allows ORA to meet its mission of ensuring that food, feed, and medical products available to the American public are safe and effective. This is accomplished by maximizing compliance of FDA regulated

products with safety and quality standards and minimizing the risks associated with the use of those products. ORA serves as the traditional "eyes and ears" of FDA through its network of investigators and laboratory analysts to enforce laws that protect and advance public health. ORA's activities are aimed at improving the safety of FDA-regulated food, feed, and medical products, and providing inspectional oversight for the administration of the Tobacco Control Act.

The initiatives proposed under the FY 2014 budget request support HHS, FDA, and Presidential public health priorities and mission-critical program activities to Transform Food Safety and Nutrition and Protect Patients.

Budget Request Details

Pay Increase (Total Program: $3,975,000)

The request for $917,329,000 in total BA for ORA reflects a total pay increase of $3,975,000 for Civilian and Commissioned Corps staff.

Adjustment to Base (Total Program: -$5,756,000 and –28 FTE)

The budget request for $917,329,000 in total budget authority for ORA also reflects a reduction to the base of -$5,756,000 and -28 FTE for FY 2014.

Foods Program

Field Activities –
FY 2012 Enacted Base: $617,049,000 (BA: $600,827,000 / UF: $16,222,000)
FY 2014 Total Increase above Base: (+$166,594,000 / 371 FTE)
FY 2014 Increase above Base for Current Law User Fees (Food Reinspection): (+$309,000 / 48 FTE)
FY 2014 Increase above Base for Current Law User Fees (Food and Feed Recall): (+$426,000 / 23 FTE)
FY 2014 Increase above Base for Proposed User Fees (International Courier): (+$735,000/ 3 FTE)
FY 2014 Increase above Base for Proposed User Fees (Cosmetics): (+$4,407,000 / 18 FTE)

FY 2014 Initiative Increases above Base:

Transforming Food Safety: Integrated Food Safety System (Proposed Food Establishment Registration and Inspection Fee +$3,360,000 / 14 FTEs)

With this investment FDA will continue to develop and implement an integrated national food safety system built on uniform regulatory program standards, strong oversight of the food supply, and sustainable multi-year infrastructure investments to provide uniform

coverage and safety oversight of the food supply. ORA will conduct the following activities with the resources in this subprogram:

- Hire two FTE to develop and administer ORA food certification programs for inspections, investigators, and analysts at FDA and its regulatory partners to ensure that all parties are performing to the national standard
- Hire three FTE to ensure programmatic objectives and implementation of the Integrated Food Safety System are coordinated and provide support for the governance structure
- Hire six FTE to serve as field State liaisons to assist the States with implementation of the Manufactured Food Regulatory Program Standards
- Hire three FTE to develop and validate certification testing instruments.

Transforming Food Safety: Standard-setting for Food Safety (Proposed Food Establishment Registration and Inspection Fee +$14,000,000 / 0 FTE)

To implement and enforce preventive controls in food processing facilities, FDA will begin training more than 1,100 ORA inspections personnel, as well as 2,300 of FDA's State, tribal, and territorial regulatory partners, in preventive controls inspections and enforcement methods to ensure that inspection personnel are prepared to conduct sound, effective inspections in the new preventive controls framework. FDA will expand the program to also train foreign regulators, third party, and industry representatives in preventive controls and other FSMA policies.

Transforming Food Safety: Import Safety – FSMA Outreach (Proposed Food Import Fee +$1,673,000 / 7 FTE)

With this investment FDA will hire seven FTE to provide outreach and education on FSMA import provisions, including outreach to the import community and other federal agencies involved in the import process.

Transforming Food Safety: Import Safety – Quality Management (Proposed Food Import Fee +$1,195,000 / 5 FTE)

With this investment FDA will hire five FTE to implement a quality management system and quality control measures for the import review process at all locations and provide dedicated quality management measures to assess and assure the consistency of the import review process.

Transforming Food Safety: Import Safety – FSMA Implementation and FSMA Effectiveness (BA +$5,245,000 / 2 FTE)

With this IT investment, FDA will continue to improve the overall effectiveness of FSMA implementation by providing cross-cutting support to achieve the FVM *Strategic Plan* goals. FSMA IT investments allow FDA to capitalize on pre- and post-market data,

scientific research, and current event information to effectively prevent public health events and ensure the safety of the food supply from farm to table. IT tools, systems, and infrastructure allow FDA to improve and expedite the identification of threats to the public health, and ultimately reduce the incidence of foodborne illness outbreaks. With these resources, FDA will conduct the following activities:

- Continue to make improvements needed to achieve more efficient information sharing among FSMA-related IT databases
- Continue to develop, maintain, and evaluate data rules for food products to begin targeting risk
- Develop data standards and methods to eliminate duplication and achieve efficiencies
- Employ technical project management and subject matter expert resources to manage and track the complex aspects of FSMA-related IT systems and databases and build critical FSMA institutional knowledge.

ORA will:

- Continue integration of IT systems
- Expand risk targeting in PREDICT by adding new data sources.

Transforming Food Safety: Integrated Food Safety System (Proposed Food Establishment Registration and Inspection Fee $1,200,000 / 5 FTE)

With this investment FDA will continue to develop and implement an integrated national food safety system built on uniform regulatory program standards, strong oversight of the food supply, and sustainable multi-year infrastructure investments to provide uniform coverage and safety oversight of the food supply. With these resources, ORA will:

- Hire four FTE to serve as Official Establishment Inventory (OEI) Coordinators for the field
- Hire one FTE with user fees to serve as Scientific Coordinators. This resource will support the States as FDA moves to national standards for laboratories.

Transforming Food Safety: Import Safety – National Call Center (Proposed Food Import Fee $7,170,000 / 30 FTE)

This investment will allow FDA to improve responsiveness to inquiries concerning the import process or the status of imports by establishing a national call center. The call center will help meet FSMA requirements for industry assistance, improve overall compliance with FSMA rules, and reduce time to solve problems.

Transforming Food Safety: Import Safety – Expanded Port / Border Hours (Proposed Food Import Fee +$39,942,000 / 54 FTE)

This investment will increase port/border coverage by adding staff and expanding hours of operation, thus providing improved screening for food safety while speeding up the overall entry admissibility process for safe products. Moreover, capital investments will be directed to acquire additional space at various border locations to support this effort. This will result in increased efficiency, improved industry/FDA communication, reduced time to resolve problems, and improved movement of trade.

Transforming Food Safety: Import Safety – Improving the Import Review Process (Proposed Food Import Fee +$18,959,000 / 6 FTE)

With this IT investment, FDA will improve information technology to enhance risk information and thus risk-based decision making for import personnel. IT tools, systems, and infrastructure allow FDA to improve and expedite the identification of threats to the public health, and ultimately reduce the incidence of foodborne illness outbreaks. With these resources, FDA will hire six FTE to implement systems and IT changes to improve the consistency, predictability, and speed of the import review process, by working with industry to enhance the quality of data FDA receives. FDA also plans to utilize Remote Access Devices to allow field staff to examine shipments and complete all required electronic submissions for data entry on site, print labels for samples collected, and complete collection reports and all necessary documentation. In addition, expedited review, examination, and sampling of products will result in a decrease in the time needed to complete an inspection by providing field staff with the ability to perform the majority of work on site. The advanced technology will provide opportunities for enhanced targeting of shipments, resulting in greater assurance in the safety of commodities physically examined by FDA. FDA will research, test, validate, and purchase analytical tools for rapid screening of products at the border. The tools will allow for improved risk analytics by permitting the targeting of products with the highest probability of being violative and the rapid release of all others into U.S. commerce.

Transforming Food Safety: Import Safety – Development of a Fee Collection System (Proposed Food Import Fee +$1,674,000 / 2 FTE)

This investment supports the design, testing, and implementation of a fee collection system to administer the import user fee program.

Transforming Food Safety: Import Safety – Comparability Assessments (BA: +$3,850,000 / 15 FTE)

This investment supports FSMA requirements by establishing an audit staff and developing comparability assessment models to oversee and conduct audits of domestic and international regulatory partners to measure performance against FDA program standards.

ORA will:

- Hire and train 15 FTE including auditors and program managers
- Implement internal procedures
- Collaborate and communicate with key stakeholders on internal integration and operational stand up of the staff
- Perform outreach with external stakeholders on final guidance documents and requirements.

Transforming Food Safety: Integrated Food Safety System – Enable Mutual Reliance on Federal, State and Local Regulatory and Public Health Partners in the Integrated Food Safety System (BA +$3,850,000 / 15 FTE)

This investment supports implementation of the Integrated Food Safety System by expanding the staff that maintain and oversee assessments and audits of State food contracts. This includes assessments of States enrolled in Manufactured Food Regulatory Program Standards. It also includes collaboration with key FDA stakeholders to enhance training and development that FDA provides to the States.

FDA will modify existing surveillance infrastructure to provide a platform for ongoing high priority pathogen detection in the food supply, expand the number of States engaged in ongoing surveillance, and expand the number and types of commodities under surveillance based on burden of illnesses estimates and food consumption patterns in the United States. FDA will partner with the CDC, USDA, and FDA centers to develop rapid strain typing methods for rapid response to foodborne outbreaks.

ORA will:

- perform 18-month assessments and begin conducting 36-month assessments of States enrolled in the MFRPS
- collaborate with key FDA stakeholders to provide feedback on assessments to be used to enhance training and development provided to the States by FDA.

Transforming Food Safety: Integrated Food Safety System (Proposed Food Establishment Registration and Inspection Fee: +$8,037,000 / 0 FTE)

With this investment FDA will continue to develop and implement an integrated national food safety system built on uniform regulatory program standards, strong oversight of the food supply, and sustainable multi-year infrastructure investments to provide more uniform coverage and safety oversight of the food supply. ORA will provide funding to Federal, State, local, territorial, and tribal regulatory and public health partners in the form of at least five States grants, contracts, cooperative agreements or inter-agency agreement between Federal agencies. Ten of the State grants, contracts, cooperative

agreements or inter-agency agreements between Federal agencies will be funded with budget authority and ten will be funded with user fees. ORA also plans to improve, strengthen, and standardize regulatory activities among all partners to ensure consistent oversight, application, and enforcement of food safety laws, and regulations.

Transforming Food Safety: Import Safety – Foreign Supplier Verification Program (Proposed Food Import Fee +$46,441,000 / 119 FTE)

This investment will support the implementation of the Foreign Supplier Verification Program, which is a comprehensive prevention-focused import food program that relies heavily on those in the food supply chain – food manufacturers, processors, packers, distributors, and importers – to provide assurances that the food imported to the United States are safe and meet regulatory requirements.

Transforming Food Safety: Import Safety – Foreign Establishment Registration Verification (Proposed Food Import Fee +$3,881,000 / 4 FTE)

This investment will allow FDA to implement registration verification of foreign firms by conducting a foreign supplier verification program. Hire four FTE to provide program oversight.

Transforming Food Safety: Planning and Response (Proposed Food Establishment Registration and Inspection Fee +$240,000 / 1 FTE)

This investment will allow FDA to respond effectively and reduce adverse public health impacts when food safety problems emerge and threaten the health of the American public. This investment will also improve FDA's ability to learn from outbreaks and other food safety incidents and thereby improve future prevention efforts. This funding will also support FDA's ability to enforce mandatory recall authority and respond immediately when a food company fails to voluntarily recall unsafe food.

FDA will work with government and industry partners to develop new traceback tools and new systems that unify information received from FDA regulatory partners and private industry. FDA will fund one FTE to develop and implement traceback procedures.

Human Drugs Program

Field Activities –
FY 2012 Enacted Base: $140,011,000 (BA: $129,993,000 / UF: $10,018,000)
FY 2014 Total Increase above Base: (+$58,530,000 / 198 FTE)
FY 2014 Increase above Base for Current Law User Fees (PDUFA): (+$890,000 / 0 FTE)
FY 2014 Increase above Base for User Fees (GDUFA): (+$53,023,000 / 173 FTE)
FY 2014 Increase above Base for User Fees (BSUFA): (+$1,322,000 / 5 FTE)

FY 2014 Increase above Base for Proposed User Fees (Medical Product Reinspection): (+$2,804,000 / 18 FTE)
FY 2014 Increase above Base for Proposed User Fees (International Courier): (+$491,000 / 2 FTE)

Biologics Program

Field Activities –
FY 2012 Enacted Base: $45,232,000 (BA: $40,513,000 / UF: $4,719,000)
FY 2014 Total Increase above Base: (+$626,000 / 4 FTE)
FY 2014 Increase above Base for Current Law User Fees (PDUFA): (+$374,000 / 0 FTE)
FY 2014 Decrease below Base for Current Law User Fees (MDUFMA): (-$320,000 / 1 FTE)
FY 2014 Increase above Base for Proposed User Fees (Medical Product Reinspection): (+$572,000 / 3 FTE)

Animal Drugs and Feeds Program

Field Activities –
FY 2012 Enacted Base: $56,869,000 (BA: $53,205,000 / UF: $3,664,000)
FY 2014 Total Increase above Base: (+$15,373,000 / 51 FTE)
FY 2014 Increase above Base for Current Law User Fees (Food Reinspection): (+$116,000 / 18 FTE)
FY 2014 Increase above Base for Current Law User Fees (Food and Feed Recall): (+$29,000 / 2 FTE)
FY 2014 Increase above Base for Current Law User Fees (ADUFA): (+$157,000 / 0 FTE)
FY 2014 Increase above Base for Current Law User Fees (AGDUFA): (+$60,000 / 1 FTE)
FY 2014 Increase above Base for Proposed User Fees (Medical Product Reinspection): (+$143,000 / 1 FTE)

FY 2014 Initiative Increases above Base:

Transforming Food Safety: Integrated Food Safety System (Proposed Registration and Inspection UF: +$240,000 / 1 FTE)

With this investment FDA will continue to develop and implement an integrated national food safety system built on uniform regulatory program standards, strong oversight of the food supply, and sustainable multi-year infrastructure investments to provide uniform coverage and safety oversight of the food supply. ORA will conduct the following activities with the resources in this subprogram:

- Hire one FTE to serve as field State liaisons to assist the States implementation of AFRPS.

Transforming Food Safety: Regulations and Guidance (Proposed Registration and Inspection UF: +$538,000 / 0 FTE)

Investments will allow FDA to implement preventive controls in feed processing facilities. ORA will conduct the following activities with the resources:

- Support the implementation and enforcement of preventive controls in feed processing facilities
- Continue to train more than 215 inspection personnel – consisting of ORA inspection personnel, as well as a portion of FDA's State, tribal, and territorial regulatory partners – in preventive controls inspections and enforcement methods.

Transforming Food Safety: Import Safety – FSMA Outreach (Proposed Import UF: +$239,000 / 1 FTE)

With this investment FDA will hire one FTE to provide outreach and education on FSMA import provisions, including outreach to the import community and other Federal agencies involved in the import process.

Transforming Food Safety: Import Safety – Quality Management (Proposed Import UF: +$239,000 / 1 FTE)

With this investment FDA will hire one FTE to implement a quality management system and quality control measures for the import review process at all locations and provide dedicated quality management measures to assess and assure the consistency of the import review process.

Transforming Food Safety: Import Safety – FSMA Implementation and FSMA Effectiveness (BA +$430,000 / 1 FTE)

With this IT investment, FDA will continue to improve the overall effectiveness of FSMA implementation by providing cross-cutting support to achieve all FVM Strategic Plan goals. FSMA IT investments allow FDA to capitalize on pre- and post-market data, scientific research, and current event information to effectively prevent public health events and ensure the safety of the food supply from farm to table. IT tools, systems, and infrastructure allow FDA to improve and expedite the identification of threats to the public health, and ultimately reduce the occurrences of foodborne illness outbreaks. With these resources, FDA will conduct the following activities:

- Continue to make improvements needed to achieve efficient information sharing among FSMA-related IT databases

- Develop, maintain, and evaluate data rules for food and feed products to begin targeting risk
- Develop data standards and methods to eliminate duplication and achieve efficiencies
- Employ technical project management and subject matter expert resources to manage and track the complex aspects of FSMA-related IT systems and databases and build critical FSMA institutional knowledge.

ORA will:

- Initiate integration of IT systems
- Begin targeting risk in PREDICT using other data sources as the data rules are completed.

Transforming Food Safety: **Integrated Food Safety System** (Proposed Registration and Inspection UF $240,000 / 1 FTE)

With this investment FDA will continue to develop and implement an integrated national food safety system built on uniform regulatory program standards, strong oversight of the food supply, and sustainable multi-year infrastructure investments to provide uniform coverage and safety oversight of the food supply. In this subprogram, ORA will hire:

One FTE to serve as a Scientific Coordinator to support the States as FDA moves to national standards for laboratories.

Transforming Food Safety: Import Safety – National Call Center (Proposed Import UF: +$717,000 / 3 FTE)

This investment will allow FDA to provide timely responses to inquiries concerning the import process or the status of imports by establishing a national call center. The call center will help meet FSMA requirement for industry assistance, improve overall compliance with FSMA rules, and reduce time to solve problems.

Transforming Food Safety: Import Safety – Expanded Port/Border (Proposed Import UF: +$4,490,000 / 6 FTE)

This investment will increase port/border coverage with increased staff and longer hours of operation, thus providing improved screening for food safety while also speeding up the overall entry admissibility process for safe products. Moreover, capital investments will be made to acquire additional space at various border locations to support this effort. This will result in increased efficiency, improved industry/FDA communication, reduced time to resolve problems, and improved movement of trade.

Transforming Food Safety: Import Safety – Improving the Import Review Process (Proposed Import UF: +$2,064,000 / 1 FTE)

With this IT investment, FDA will improve information technology to enhance risk information and thus risk-based decision making for import personnel. IT tools, systems, and infrastructure allow FDA to improve and expedite the identification of threats to the public health, and ultimately reduce the incidence of foodborne illness outbreaks. With these resources, FDA will conduct the following activities:

- Hire one FTE to implement systems and IT changes to improve the consistency, predictability, and speed of the import review process, by working with industry to enhance the quality of data FDA receives.
- Utilize Remote Access Devices to allow field staff to examine shipments and complete all required electronic submissions for data entry on site, print labels for samples collected, and complete collection reports and all necessary documentation. In addition, expedited review, examination, and sampling of products will result in a decrease in the time needed to complete an inspection by providing field staff with the ability to perform the majority of work on site. The advanced technology will provide opportunities for enhanced targeting of shipments, resulting in greater assurance in the safety of commodities physically examined by FDA.

Transforming Food Safety: Import Safety – Foreign Supplier Verification Program (Proposed Import UF: +$5,107,000 / 13 FTE)

This investment will support the implementation of the Foreign Supplier Verification Program (FSVP), which is a comprehensive prevention-focused import food and feed safety program that relies heavily on those in the food supply chain – food and feed manufacturers, processors, packers, distributors, and importers – to provide assurances that the food and feed imported to the United States are safe and meet regulatory requirements.

Transforming Food Safety: Import Safety – Foreign Establishment Registration Verification (Proposed Import UF: +$564,000 / 1 FTE)

This investment will allow FDA to implement registration verification of foreign firms by conducting a foreign supplier verification program. Hire one FTE to provide program oversight.

Devices and Radiological Health Program

Field Activities –
FY 2012 Enacted Base: $95,334,000 (BA: $81,197,000 / UF: $14,137,000
FY 2014 Total Increase above Base: (+$8,182,000 / 36 FTE)
FY 2014 Increase above Base for Current Law User Fees (MDUFMA): (+$853,000 / -3 FTE)

FY 2014 Increase above Base for User Fees (MQSA): (+$0/ 0 FTE)
FY 2014 Increase above Base for Proposed User Fees (Medical Product Reinspection): (+$3,651,000 / 24 FTE)
FY 2014 Increase above Base for Proposed User Fees (International Courier): (+$3,678,000 / 15 FTE)

Tobacco Control Act Program

Field Activities –
FY 2012 Enacted Base: $6,250,000 (All UF)
FY 2014 Total Increase above Base: (+$8,739,000 / 37 FTE)
FY 2013-2014 Increase above Base for Current Law User Fees (Tobacco): (+$8,739,000 / 37 FTE)

Combined Field Activities – ORA
Program Activity Data

Field Foods Program Activity Data (PAD)

Field Foods Program Workload and Outputs	FY 2012 Actual		FY 2013 [1] Estimate	FY 2014 Request
FDA WORK				
DOMESTIC INSPECTIONS				
UNIQUE COUNT OF FDA DOMESTIC FOOD ESTABLISHMENT INSPECTIONS	***10,086***		***10,326***	***10,326***
Domestic Food Safety Program Inspections	7,523		Activities no longer planned to this level due to enactment of FSMA and alignment of resources into only high and low risk categories.	Activities no longer planned to this level due to enactment of FSMA and alignment of resources into only high and low risk categories.
Imported and Domestic Cheese Program Inspections	266			
Domestic Low Acid Canned Foods/ Acidified Foods Inspections	382			
Domestic Fish & Fishery Products (HACCP) Inspections	1,422			
Import (Seafood Program Including HACCP) Inspections	252			
Juice HACCP Inspection Program (HACCP)	259			
Interstate Travel Sanitation (ITS) Inspections	1,053			
Domestic Field Exams/Tests	3,513		3,945	3,945
Domestic Laboratory Samples Analyzed	10,621		11,300	11,300
FOREIGN INSPECTIONS				
UNIQUE COUNT OF FDA FOREIGN FOOD ESTABLISHMENT INSPECTIONS	***1,347***	[2]	***1,200***	***1,200***
All Foreign Inspections	1,347		1,200	1,200
TOTAL UNIQUE COUNT OF FDA FOODS ESTABLISHMENT INSPECTIONS	***11,433***		***11,526***	***11,526***
IMPORTS				
Import Field Exams/Tests	171,783		160,200	160,200
Import Laboratory Samples Analyzed	29,966		35,300	35,300
Import Physical Exam Subtotal	**201,749**		**195,500**	**195,500**
Import Line Decisions	10,805,094		11,482,234	12,201,809
Percent of Import Lines Physically Examined	1.87%		1.70%	1.60%
Prior Notice Security Import Reviews				
(Bioterrorism Act Mandate)	81,888		80,000	80,000
STATE WORK				
UNIQUE COUNT OF STATE CONTRACT FOOD ESTABLISHMENT INSPECTIONS	***9,306***		***10,523***	***10,523***
UNIQUE COUNT OF STATE PARTNERSHIPS FOOD ESTABLISHMENT INSPECTIONS	***430***		***273***	***273***
State Contract Food Safety (Non HACCP) Inspections	8,161		9,318	9,318
State Contract Domestic Seafood HACCP Inspections	1,062		1,104	1,104
State Contract Juice HACCP	69		103	103
State Contract LACF	76		68	68
State Partnership Inspections	430		273	273
State Contract Foods Funding	$12,699,510		13,076,000	13,076,000
Number of FERN State Laboratories	19		19	19
Number of Food Safety State Laboratories	15		15	15
Annual FERN State Cooperative Agreements/Operations Funding	$16,136,000		$18,455,000	$18,455,000
Total State & Annual FERN Funding	**$28,835,510**		**$31,531,000**	**$31,531,000**
GRAND TOTAL FOOD ESTABLISHMENT INSPECTIONS	***21,169***		***22,322***	***22,322***

[1] Spending authority has been adjusted pursuant to PL 112-175, Section 101(c) for the applicable user fee programs.

[1] For investigators hired with FY 2014 BA funding received through the Office of International Programs (OIP) for the China Import Safety Initiative, the full performance year is FY 2016. During the full performance year (FY 2016), the FY 2014 funding increase for inspections will allow OIP to conduct an additional 135 foreign food safety inspections. Please also see the FDA Headquarters /OIP narrative for further information.

[2] The FY 2012 actual unique count of foreign inspections includes 42 OIP inspections (10 for China and 32 for India).

Combined Field Activities – ORA
Program Activity Data

Field Cosmetics Program Activity Data (PAD)

Field Cosmetics Program Workload and Outputs	FY 2012 Actual	FY 2013 Estimate	FY 2014 Request
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA COSMETICS ESTABLISHMENT INSPECTIONS	***160***	***100***	***100***
Domestic Inspections	160	100	100
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA COSMETICS ESTABLISHMENT INSPECTIONS	***10***	***0***	***0***
Foreign Inspections	10	0	0
IMPORTS			
Import Field Exams/Tests	2,632	1,600	1,600
Import Laboratory Samples Analyzed	543	540	540
Import Physical Exam Subtotal	**3,175**	**2,140**	**2,140**
Import Line Decisions	2,349,615	2,602,764	2,883,187
Percent of Import Lines Physically Examined	0.14%	0.08%	0.07%
GRAND TOTAL COSMETICS ESTABLISHMENT	***170***	***100***	***100***

Combined Field Activities – ORA
Program Activity Data

Field Human Drugs Program Activity Data (PAD)

Field Human Drugs Program Workload and Outputs	FY 2012 Actual	FY 2013[1] Estimate	FY 2014 Request
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC HUMAN DRUG ESTABLISHMENT INSPECTIONS	***2,120***	***1,856***	***1,856***
Pre-Approval Inspections (NDA)	116	171	171
Pre-Approval Inspections (ANDA)	107	216	216
Bioresearch Monitoring Program Inspections	510	563	563
Drug Processing (GMP) Program Inspections	1,134	591 [2]	591
Compressed Medical Gas Manufacturers Inspections	280	295	295
Adverse Drug Events Project Inspections	100	120	120
OTC Monograph Project and Health Fraud Project Inspections	77	79	79
Domestic Laboratory Samples Analyzed	1,450	1,450	1,450
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN HUMAN DRUG ESTABLISHMENT INSPECTIONS	***813*** [1]	***952***	***999*** [3]
Foreign Pre-Approval Inspections (NDA) incl PEPFAR	158	98	98
Foreign Pre-Approval Inspections (ANDA) incl PEPFAR	108	83	83
Foreign Bioresearch Monitoring Program Inspections incl PEPFAR	196	240	255 [4]
Foreign Drug Processing (GMP) Program Inspections	588	797 [2]	843 [5]
Foreign Adverse Drug Events Project Inspections	3	15	15
TOTAL UNIQUE COUNT OF FDA HUMAN DRUG ESTABLISHMENT INSPECTIONS	***2,933***	***2,808***	***2,855***
IMPORTS			
Import Field Exams/Tests	8,134	7,200	7,200
Import Laboratory Samples Analyzed	493	490	490
Import Physical Exam Subtotal	**8,627**	**7,690**	**7,690**
Import Line Decisions	592,591	734,933	911,465
Percent of Import Lines Physically Examined	1.46%	1.05%	0.84%
STATE WORK			
UNIQUE COUNT OF STATE PARTNERSHIP HUMAN DRUG ESTABLISHMENT INSPECTIONS.	***100***	***100***	***100***
State Partnership Inspections: Compressed Medical Gas Manufacturers Inspections	83	83	83
State Partnership Inspections: GMP Inspections	17	17	17
GRAND TOTAL HUMAN DRUG ESTABLISHMENT INSPECTIONS	***3,033***	***2,908***	***2,955***

[1] Spending authority has been adjusted pursuant to PL 112-175, Section 101(c) for the applicable user fee programs.

[1] The FY 2012 actual unique count of foreign inspections includes 43 OIP inspections (2 for China and 41 for India).

[2] The FY 2013 planned mix of domestic versus foreign GMP inspections shifts quite a few more inspections into the foreign arena, with a corresponding decrease to domestic GMP inspections in comparison to the FY 2012 actuals, but the overall coverage is not changing, This is being done to achieve greater parity of the foreign versus domestic inspections and thus level out the inspection coverage.

[3] For investigators hired with FY 2014 BA funding received through the Office of International Programs (OIP) for the China Import Safety Initiative, the full performance year is FY 2016. During the full performance year (FY 2016), the FY 2014 funding increase for inspections will allow OIP to conduct an additional 120 foreign human drug safety inspections. Please also see the FDA Headquarters /OIP narrative for further information.

[4] For ORA investigators hired with FY 2011 enacted increases, the full performance year is FY 2014 for foreign generic drug bioequivalence laboratory inspections. During the full performance year (FY 2014), the FY 2011 funding increases for inspections ORA to conduct an additional 15 foreign bioresearch monitoring inspections.

[5] For ORA investigators hired with FY 2011 enacted increases, the full performance year is FY 2014. During the full performance year (FY 2014), the FY 2011 funding increases for inspections will allow ORA to conduct an additional 46 foreign GMP surveillance inspections.

Combined Field Activities – ORA
Program Activity Data

Field Biologics Program Activity Data (PAD)

Field Biologics Program Workload and Outputs	FY 2012 Actuals	FY 2013 [1] Estimate		FY 2014 Request
FDA WORK				
DOMESTIC INSPECTIONS				
UNIQUE COUNT OF FDA DOMESTIC BIOLOGICS ESTABLISHMENT INSPECTIONS	***1,972***	***2,047***		***2,047***
Bioresearch Monitoring Program Inspections	98	100		100
Blood Bank Inspections	1,061	1,060		1,060
Source Plasma Inspections	190	194		194
Pre-License, Pre-Market Inspections	7	7		7
GMP Inspections	26	28		28
GMP (Device) Inspections	7	7		7
Human Tissue Inspections	593	661	[1]	661
FOREIGN INSPECTIONS				
UNIQUE COUNT OF FDA FOREIGN BIOLOGICS ESTABLISHMENT INSPECTIONS	***50***	***47***		***47***
Bioresearch Monitoring Program Inspections	11	11		11
Foreign Human Tissue Inspections	1	0		0
Blood Bank Inspections	8	8		8
Pre-License Inspections	2	2		2
GMP Inspections	22	20		20
TOTAL UNIQUE COUNT OF FDA BIOLOGIC ESTABLISHMENT INSPECTIONS	***2,022***	***2,094***		***2,094***
IMPORTS				
Import Field Exams/Tests	45	45		45
Import Line Decisions	65,469	79,771		97,198
Percent of Import Lines Physically Examined	0.07%	0.06%		0.05%
GRAND TOTAL BIOLOGICS ESTABLISHMENT INSPECTIONS	***2,022***	***2,094***		***2,094***

[1] Spending authority has been adjusted pursuant to PL 112-175, Section 101(c) for the applicable user fee programs.

[1] For ORA investigators hired with FY 2011 BA enacted increases, the full performance year is FY 2013 for domestic human tissue inspections. During the full performance year (FY 2013), the FY 2011 BA enacted funding increases for inspections will allow ORA to conduct an additional 68 domestic human tissue inspections.

Combined Field Activities – ORA
Program Activity Data

Field Animal Drugs & Feeds Program Activity Data (PAD)

Field Animal Drugs and Feeds Program Workload and Outputs	FY 2012 Actual			FY 2013 [1] Estimate			FY 2014 Request		
	Total	Animal Drugs	Feeds	Total	Animal Drugs	Feeds	Total	Animal Drugs	Feeds
FDA WORK									
DOMESTIC INSPECTIONS									
UNIQUE COUNT OF FDA DOMESTIC ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***2,108***	***303***	***1,833***	***1,792***	***299***	***1,524***	***1,792***	***299***	***1,524***
Pre-Approval /BIMO Inspections	67	67	0	79	79	0	79	79	0
Drug Process and New ADF Program Inspections	238	238	0	222	222	0	222	222	0
BSE Inspections	1,628	0	1,628	1,205	0	1,205 [2]	1,205	0	1,205
Feed Contaminant Inspections	18	0	18	25	0	25	25	0	25
Illegal Residue Program Inspections	338	0	338	473	0	473	473	0	473
Feed Manufacturing Program Inspections	234	0	234	141	0	141	141	0	141
Domestic Laboratory Samples Analyzed	1,689	1	1,688	2,458	26	2,432	2,458	26	2,432
FOREIGN INSPECTIONS									
UNIQUE COUNT OF FDA FOREIGN ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***85***	***64*** [1]	***21***	***76***	***69***	***6***	***76***	***69***	***6***
Foreign Pre-Approval/Bioresearch Monitoring Program Inspections	25	25	0	45	45	0	45	45	0
Foreign Drug Processing and New ADF Program Inspections	47	47	0	33	33	0	33	33	0
Foreign Feed Inspections	12	0	12	7	0	7	7	0	7
BSE Inspections	11	0	11	0	0	0	0	0	0
TOTAL UNIQUE COUNT OF FDA ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***2,193***	***367***	***1,854***	***1,868***	***368***	***1,530***	***1,868***	***368***	***1,530***
IMPORTS									
Import Field Exams/Tests	5,862	412	5,450	3,600	185	3,415	3,600	185	3,415
Import Laboratory Samples Analyzed	644	4	640	750	2	748	750	2	748
Import Physical Exam Subtotal	**6,506**	**416**	**6,090**	**4,350**	**187**	**4,163**	**4,350**	**187**	**4,163**
Import Line Decisions	331,505			385,635			448,604		
Percent of Import Lines Physically Examined	1.96%			1.13%			0.97%		
STATE WORK									
UNIQUE COUNT OF STATE CONTRACT ANIMAL FEEDS ESTABLISHMENT INSPECTIONS	***4,456***	***0***	***4,456***	***5,045***	***0***	***5,045***	***5,045***	***0***	***5,045***
UNIQUE COUNT OF STATE PARTNERSHIPS ANIMAL FEEDS ESTABLISHMENT INSPECTIONS	***126***	***0***	***126***	***300***	***0***	***300***	***300***	***0***	***300***
UNIQUE COUNT OF STATE COOPERATIVE AGREEMENT ANIMAL FEEDS ESTABLISHMENT INSPECTIONS	***584***	***0***	***584***	***600***	***0***	***600***	***600***	***0***	***600***
State Contract Inspections: BSE	4,412	0	4,412	5,000	0	5,000	5,000	0	5,000
State Contract Inspections: Feed Manufacturers	414	0	414	320	0	320	320	0	320
State Contract Inspections: Illegal Tissue Residue	237	0	237	412	0	412	412	0	412
State Partnership Inspections: BSE and Other	127	0	127	151	0	151	151	0	151
State Cooperative Agreement BSE Inspections	584	0	584	600	0	600	600	0	600
State Contract Animal Drugs/Feeds Funding	2,604,440	$0	$2,604,440	2,782,770	$0	$2,782,770	2,782,770	0	$2,782,770
BSE Cooperative Agreement Funding	2,696,570	$0	$2,696,570	2,572,920	$0	$2,572,920	2,572,920	0	$2,572,920
State Contract Tissue Residue Funding	592,680	$0	$592,680	686,440	$0	$686,440	686,440	0	$686,440
Total State Funding	**$5,893,690**	**$0**	**$5,893,690**	**$6,042,130**	**$0**	**$6,042,130**	**$6,042,130**	**$0**	**$6,042,130**
GRAND TOTAL ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***7,359***	***367***	***7,020***	***7,213***	***368***	***6,875***	***7,213***	***368***	***6,875***

[1] Spending authority has been adjusted pursuant to PL 112-175, Section 101(c) for the applicable user fee programs.

[1] The FY 2012 actual unique count of foreign inspections includes one OIP inspection (in India for Animal Drugs).

[2] The decrease in inspections (423) from FY 2012 is due to program resources being shifted to the Tissue Residue program. The change in inspections is not equivalent for both categories because the time it takes to conduct a tissue residue inspection is longer than the time required to conduct a BSE inspection with the same level of resources, thus resulting in fewer inspections conducted by comparison.

Combined Field Activities – ORA
Program Activity Data

Field Devices Program Activity Data (PAD)

Field Devices Program Workload and Outputs	FY 2012 Actuals		FY 2013[1] Estimate		FY 2014 Request
FDA WORK					
DOMESTIC INSPECTIONS					
UNIQUE COUNT OF FDA DOMESTIC DEVICES ESTABLISHMENT INSPECTIONS	***2,741***		***2,864***		***2,864***
Bioresearch Monitoring Program Inspections	295		300		300
Pre-Market Inspections	54		67		67
Post-Market Audit Inspections	44		34		34
GMP Inspections	1,790		1,592	[2]	1,592
Inspections (MQSA) FDA Domestic (non-VHA)	521		723		723
Inspections (MQSA) FDA Domestic (VHA)	43		43		43
Domestic Radiological Health Inspections	90		205		205
Domestic Field Exams/Tests	215		215		215
Domestic Laboratory Samples Analyzed	183		183		183
FOREIGN INSPECTIONS					
UNIQUE COUNT OF FDA FOREIGN DEVICES ESTABLISHMENT INSPECTIONS	***453***	[1]	***603***		***603***
Foreign Bioresearch Monitoring Inspections	10		25		25
Foreign Pre-Market Inspections	27		31		31
Foreign Post-Market Audit Inspections	31		19		19
Foreign GMP Inspections	386		519	[2]	519
Foreign MQSA Inspections	14		15		15
Foreign Radiological Health Inspections	23		45		45
TOTAL UNIQUE COUNT OF FDA DEVICE ESTABLISHMENT INSPECTIONS	***3,194***		***3,467***		***3,467***
IMPORTS					
Import Field Exams/Tests	18,821		18,821		18,821
Import Laboratory Samples Analyzed	1,123		1,123		1,123
Import Physical Exam Subtotal	**19,944**		**19,944**		**19,944**
Import Line Decisions	13,651,985		19,445,808		27,698,496
Percent of Import Lines Physically Examined	0.15%		0.10%		0.07%
STATE WORK					
UNIQUE COUNT OF STATE CONTRACT DEVICES ESTABLISHMENT INSPECTIONS	***7,918***		***7,929***		***7,929***
UNIQUE COUNT OF STATE PARTNERSHIPS DEVICE ESTABLISHMENT INSPECTIONS	**59**		**59**		**59**
Inspections (MQSA) by State Contract	6,792		6,800		6,800
Inspections (MQSA) by State non-Contract	1,107		1,110		1,110
GMP Inspections by State Contract	19		19		19
State Partnership GMP Inspections	59		59		59
State Contract Devices Funding	81,685		85,000		85,000
State Contract Mammography Funding	8,692,710		9,127,350		9,127,350
Total State Funding	**$8,774,395**		**$9,212,350**		**$9,212,350**
GRAND TOTAL DEVICES ESTABLISHMENT INSPECTIONS	***11,171***		***11,455***		***11,455***

[1] Spending authority has been adjusted pursuant to PL 112-175, Section 101(c) for the applicable user fee programs.

[1] The FY 2012 actual unique count of foreign inspections includes 11 OIP inspections (10 for China and 1 for India).

[2] The FY 2013 planned mix of domestic versus foreign GMP inspections shifts quite a few more inspections into the foreign arena, with a corresponding decrease to domestic GMP inspections in comparison to the FY 2012 actuals, but the overall coverage is not changing, This is being done to achieve greater parity of the foreign versus domestic inspections and thus level out the inspection coverage.

Tobacco

TOBACCO CONTROL ACT PROGRAM

The following table displays funding and full time equivalent (FTE) staffing levels for FY 2012 through FY 2014.

FDA Program Resources Table[45]

(Dollars in thousands)

	FY 2012 Enacted	FY 2012 Actual	FY 2013 CR	FY 014 Request	FY 2014 +/- FY 2012 Enacted
Program Level	**$454,751**	**$277,136**	**$457,534**	**$501,476**	**$46,725**
Center	$448,501	$271,695	$451,246	$486,487	$37,986
FTE	366	346	482	570	224
Field	$6,250	$5,441	$6,288	$14,989	$8,739
FTE	26	33	41	70	37
Program Level FTE	**392**	**379**	**523**	**640**	**261**
User Fees	**$454,751**	**$277,136**	**$457,534**	**$501,476**	**$46,725**
Center	$448,501	$271,695	$451,246	$486,487	$37,986
FTE	366	346	482	570	224
Field	$6,250	$5,441	$6,288	$14,989	$8,739
FTE	26	33	41	70	37
User Fees FTE	**392**	**379**	**523**	**640**	**261**

The FDA Tobacco Control Act Program operates under the following legal authorities:

Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321-399)
The Family Smoking Prevention and Tobacco Control Act of 2009 (P.L. 111-31)
The Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333)
Public Health Service Act of 1944 (42 U.S.C. 201)
Federal Advisory Committee Act (FACA) of 1972, as amended

Allocation Method: Direct Federal/Intramural; Competitive Grants; Contracts

[45] Spending authority has been adjusted pursuant to PL 112-175, Section 101(c) for the applicable user fee programs.

Program Description and Accomplishments

The Food and Drug Administration's (FDA) Center for Tobacco Products (CTP) oversees the implementation of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). FDA executes its regulatory and public health responsibilities in three subprograms that support its strategic objectives:

- Reducing initiation of tobacco product use
- Decreasing the harms of tobacco products, and
- Encouraging cessation among tobacco product users.

To achieve its goals, FDA relies on its statutory authorities to regulate the manufacturing, marketing, and distribution of tobacco products. Some of these authorities include:

- Requiring tobacco product manufacturers, importers, and distributors to register with FDA and requiring manufacturers and importers to provide a list of tobacco products they sell
- Requiring industry reporting of tobacco product ingredient and constituent data
- Inspecting tobacco product establishments, including retailers, to assure compliance with FDA laws and tobacco product regulations
- Prohibiting tobacco product labeling or advertising or other marketing that is inaccurate, false, or misleading
- Establishing tobacco product standards to protect the public health
- Issuing regulations for the manufacture of tobacco products
- Strengthening health warnings for cigarettes and smokeless tobacco products
- Initiating enforcement actions for violations of the Tobacco Control Act.

FDA's Office of Regulatory Affairs (ORA) Field offices support Tobacco Control Act Program activities by:

- Collecting and analyzing samples of tobacco products to ensure compliance with the requirements of the Tobacco Control Act and other applicable regulations
- Providing training to ORA field employees and assisting in the development of training materials for employees working under FDA contracts with U.S. States and Territories to conduct tobacco retail inspections on behalf of the agency
- Conducting investigations and inspections to assess compliance with the requirements of the Tobacco Control Act and other applicable regulations.

Reducing Youth Initiation to Tobacco – Center Activities
Base Amount: $272,348,000 (All User Fees)

Public Health Focus

In order to meet its goal of reducing initiation of tobacco use, especially by young people, FDA will focus on the following areas:

- Dramatically reducing youth access to tobacco products by deeming all tobacco products to be subject to FDA's tobacco product authorities and vigorously enforcing the law
- Using its statutory authorities to communicate broadly and effectively about tobacco product content and harms to youth, especially those most at risk of becoming addicted tobacco users
- Expanding the Tobacco Retail Inspection Program to conduct compliance check inspections of retail establishments that sell tobacco products.

As part of ongoing efforts to expand the Tobacco Retail Inspection Program, FDA recently awarded six additional tobacco retail inspection contracts to Guam, Idaho, Montana, Northern Mariana Islands, Puerto Rico, and South Carolina. FDA now contracts with 44 U.S. States, territories, and the District of Columbia to conduct inspections and expects additional awards to be made in the future.

In FY 2013, the Tobacco Retail Inspection Program will also:

- Increase the total number of inspections of tobacco retailers within U.S. States and Territories
- Conduct quality assessments of performance under the State contracts
- Maintain effective internal controls that meet the objectives of the Federal Managers' Financial Integrity Act to ensure effective and efficient operations and compliance with applicable laws and regulations
- Continue to issue Warning Letters and Civil Money Penalty actions, and other applicable enforcement actions against retailers that violate the law and applicable regulations
- When such regulations become effective, include newly-deemed tobacco products in the State Retail Enforcement Program.

To encourage voluntary compliance with the Tobacco Control Act, FDA continues to educate retailers about their responsibilities to protect the Nation's young people. These efforts include outreach to small businesses and to those in minority communities. In FY 2013, FDA will hold regular compliance education webinars during which retailers will be provided an opportunity to ask questions about FDA regulatory activities. FDA also plans to conduct regular compliance education webinars directed towards small manufacturers to provide information about the Tobacco Control Act, FDA regulations, and other activities, including what to expect during an FDA inspection of a manufacturing facility.

FDA will continue its efforts to prevent youth from using the tobacco products it regulates, currently cigarettes, cigarette tobacco, roll-your-own, and smokeless tobacco, and encouraging youths that use tobacco products to quit. As authorized by the Tobacco

Control Act, in FY 2013, these activities will involve a full range of actions associated with planning, developing, producing, and delivering consumer-based programs, strategies, and materials for national public education campaigns. FDA will also obtain technical services for strategic planning, development, execution, and assessment of multimedia public education campaigns designed to reduce tobacco use among youth aged 12-17.

Public Health Outcome

In FY 2013, FDA will continue to educate the public about tobacco products and their harms. FDA will develop and launch several public health education campaigns to educate the public about:

- Harmful and potentially harmful constituents of tobacco products
- Statutory requirement to require health warnings on cigarettes and smokeless tobacco products packages and in advertising
- Restrictions on marketing and sales of tobacco products to youth
- Use of misleading descriptors like “light,” “low,” and “mild” on tobacco products
- Other FDA regulatory authorities as they are implemented.

Examples of these public health education programs include:

- Development of comprehensive youth and young adult public health education programs designed to inform them about the harms of tobacco product use and the potential for addiction
- Support for a HHS-wide effort to provide accurate messages about tobacco products and the harms resulting from its use
- Development of a comprehensive benchmark and tracking evaluation program that will assess the effectiveness of FDA public health education programs.

On November 21, 2012 FDA awarded contracts s to two small business vendors to produce public education campaigns tailored to at-risk African American, Hispanic, and Asian/Pacific Islander teens, teens who identify as Lesbian, Gay, Bisexual or Transsexual, and teens who reside in rural areas. In December 2012, FDA awarded two more contracts targeting general market youth ages 12-17 who have never tried or who are intermittent users of tobacco products. These awards will allow FDA to begin utilizing comprehensive, multi-media public education campaigns to educate at-risk, underage youth about the dangers of FDA-regulated tobacco products to prevent initiation.

Reducing Youth Initiation to Tobacco – Field Activities
Base Amount: $6,250,000 (All User Fees)

Public Health Focus

To ensure compliance with the Tobacco Control Act, FDA conducts surveillance, investigations, inspections, sample collections, and detention/refusal of tobacco products.

ORA has established and continues to maintain a testing laboratory at the Southeast Regional Laboratory (SRL) with expertise and capacity to analyze tobacco products. The ORA SRL laboratory has been acquiring specific testing equipment such as mass spectrometers and smoke machines and continues to work towards developing multi-residue flavor methods to detect unpermitted compounds that impart a characterizing flavor to tobacco products. In addition, SRL, in conjunction with ORA headquarters, has been collaborating with other federal laboratory partners to leverage information, intelligence and experience. Also of note, ORA's Forensic Chemistry Center (FCC) laboratory will provide support to the Office of Criminal Investigations (OCI) to identify criminal violations in tobacco-product related cases.

In FY 2012, ORA continued to perform inspections of registered tobacco product establishments to determine their compliance with the laws and regulations enforced by FDA. During those inspections, ORA determined compliance with the provisions of the law to include registration, product and ingredient listing, packaging, labeling, and advertising requirements, and marketing authorization for new or modified risk tobacco products.

Public Health Outcome

ORA carries out a multi-tiered approach towards enforcing the requirements of the Tobacco Control Act. In addition to inspecting registered tobacco establishments, ORA conducts investigations at sports and entertainment events to ensure tobacco manufacturers promote and distribute their products in accordance with the law. These inspections and investigations help to ensure that the regulated tobacco industry complies with the tobacco provisions of the Food Drug &Cosmetic Act (FD&C Act) and its implementing regulations.

Furthermore, working with CTP, ORA issued two import alerts related to the restrictions on the terms "low," "mild," and "light" to describe tobacco products and for prohibited candy or fruit flavored cigarettes to identify, detain, and refuse these products being offered for import. This effort puts into place a mechanism for detention without physical examination of imported tobacco products found to be adulterated or which otherwise do not conform to the same regulatory requirements as domestically-manufactured tobacco products.

Working collaboratively with CTP, ORA continues to expand its program to train investigators to perform tobacco manufacturer inspections, thus ensuring that the investigators are well-trained in tobacco product inspection techniques.

ORA's commissioning program allows those entities to perform tobacco retail inspection on FDA's behalf and share information related to these retail inspections. As of September 30, 2012, officials have been commissioned in 37 states and the District of Columbia. FDA awarded six contracts to U.S. States and Territories in FY 2012 and they are currently going through the commissioning process.

From October 1, 2011 through September 30, 2012, tobacco-commissioned officials had conducted over 87,000 tobacco retail inspections.

On the analytical front, ORA has been working on establishing tobacco flavors methods so that the ban on characterizing flavors under the Tobacco Control Act can be enforced through special testing assignments.

During FY 2012, ORA's Office of Criminal Investigations (OCI) made 16 tobacco related arrests and secured one tobacco related conviction.
Some representative cases include:

- **Foreign-based distributor of counterfeit tobacco products** – In June of 2012, a Chinese national was indicted in Providence, Rhode Island for selling and importing counterfeit tobacco products into the United States from China. The subject has been detained since his arrest in Miami on June 4, 2012, by FDA/OCI. OCI agents, acting in an undercover capacity, arranged for the shipment from China to the United States of a 20-foot cargo container containing 17 pallets of alleged counterfeit Marlboro cigarettes, worth in excess of one million dollars.

- **Domestic-based distributor of counterfeit tobacco products -** In July 2012, two individuals were arrested for the distribution of counterfeit tobacco and pharmaceutical products in the Los Angeles, California area. During this multi-agency effort, OCI agents and other participating agencies and officers executed search warrants in East Los Angeles and the surrounding area resulting in the seizure of nearly $2,000,000 in counterfeit cigarettes and $100,000 in counterfeit Viagra pills.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
280005: Total number of compliance check inspections of retail establishments in States under contract. *(Outcome)*	FY 2012: 87,455 Target: 84,000 (Target Exceeded)	84,000	80,000	- 4,000

Reducing Tobacco Product Harms – Center Activities

Base Amount: $94,358,000 (All User Fees)

Public Health Focus

FDA is dedicated to reducing tobacco harms by engaging in and supporting numerous research and scientific endeavors. The research will expand the scientific evidence needed to implement several authorities specified in the Tobacco Control Act and will also help assess the impact of regulatory actions. This research is also consistent with the HHS Strategic Plan and the Secretary's strategic initiatives which seek to prevent and reduce tobacco use through accelerated research to expand the science base and monitor progress.

Public Health Outcome

FDA will continue to expand funding for biomedical research collaborations within FDA and in collaboration with the National Institutes of Health (NIH) and Centers for Disease Control and Prevention (CDC) in the areas of:

- Tobacco product addictiveness
- Tobacco product chemistry and engineering related to abuse liability thresholds
- Measurement and standards for assessment of harmful ingredients
- Biomarkers for health effects of exposure to tobacco ingredients
- Cognitive and behavioral determinants of tobacco initiation/maintenance and cessation related to marketing and health warnings
- Expanding the foundation of knowledge of the chemistry, toxicology, health and public health impact of new and emerging tobacco products and the potential public health impact of tobacco product regulations.

In April 2012, FDA published the harmful and potentially harmful tobacco product constituent (HPHC) list which established a listing of 93 tobacco product and tobacco smoke constituents FDA believes are harmful or potentially harmful to health.

Also in April 2012, FDA published the draft guidance for industry on Reporting HPHCs in Tobacco Products and Tobacco Smoke as required by section 904(a)(3) of the FD&C Act which provides assistance for reporting the quantities of HPHCs.

FDA will continue to award research contracts in addition to expanding funding for tobacco regulatory science research within FDA and in collaboration with NIH and CDC.

In FY 2013, FDA will continue to invest in broadening the cadre of regulatory science leaders needed to address tobacco product regulation today and into the future. FDA will expand the FDA Tobacco Regulatory Science Fellowship Program in conjunction with the National Academy of Sciences' Institute of Medicine and initiate a research training grant program in conjunction with NIH. These programs will help ensure that there is a diverse

pool of highly trained professionals available to address the tobacco regulatory science needs well into the future both by attracting mid-career and experienced professionals to move into tobacco product regulatory science as well as to attract young investigators into tobacco regulatory science research at different stages in their research careers.

Additionally, FDA will continue review of regulatory submissions from the tobacco industry, including Substantial Equivalence Reports and requests for Substantial Equivalence Exemptions as well as New Tobacco Product applications and Modified Risk Tobacco Product applications following published FDA guidance documents intended to protect the public health.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
280002: Develop a scientific base to understand and reduce harm from tobacco products by initiating a testing program to support tobacco product standards development, which will include a review of tobacco product ingredients. *(Output)*	FY 2012: Established a list of 93 harmful and potentially harmful constituents to health, publishing it in the Federal Register on April 3, 2012. (Target Met)	Establish a list of harmful and potentially harmful ingredients and constituents in tobacco products and tobacco smoke. TPSAC to issue a report on dissolvable tobacco products. Issue a proposed rule or draft guidance that establishes requirements or contains recommendations regarding the scientific evidence required for assessment and ongoing review of modified risk products.	Develop at least one draft guidance identifying methods which should be used for measuring high priority HPHCs. Continue to review substantial equivalence reports, pre-market tobacco product applications, and modified risk tobacco product submissions	NA

Encouraging Cessation - Center Activities

Base Amount: $81,795,000 (All User Fee)

Public Health Focus

FDA is promoting the public health by leading comprehensive, science-based efforts to educate the nation about the dangers of tobacco products. Consistent with the HHS

Strategic Plan and the Secretary's strategic initiatives, FDA seeks to prevent and reduce tobacco use through change in social norms related to tobacco use, amount other things. All aspects of FDA's three strategic priorities (decreasing initiation of tobacco product use, decreasing the harms of tobacco products, and encouraging cessation among tobacco product users) have important public health education components with respect to implementing the Tobacco Control Act.

Public Health Outcome

FDA will continue to allocate significant resources to enforce statutory requirements of the Tobacco Control Act. FDA will continue to review new submissions and supplements involving health warning plans for smokeless tobacco products.

In addition, FDA continues to engage all stakeholders about the Tobacco Control Act and how to comply with its requirements. Specifically, FDA is providing "Break the Chain of Tobacco Addiction" educational and display materials at no charge to U.S. retailers to promote compliance with the law. The materials were developed with input from retail establishments and include posters, flyers, and syndicated content for retailer websites. FDA is creating customized tools that enable the public and other stakeholders to better access and understand the Tobacco Control Act in a plain language format. This includes plain language summaries, interactive timelines, and customized searches by audience, type of tobacco product, and topic.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
280004: Educate stakeholders and the general public about the new tobacco products regulations and the health effects of tobacco use. *(Output)*	FY 2012 Target: Implemented and refined education program directed to retailers and the general public, especially youth. (Target Met)	Continue to implement and improve programs designed to educate the public and industry.	Continue to implement and improve programs designed to educate the public and industry. Expand consumer health education in support of FDA's regulatory authorities.	NA

Information Technology Investments –Tobacco Program Activities (Base Amount displayed as a non-add item: $21,965,994)

CTP's Information Technology (IT) investment portfolio represents a management analytic for IT capital assets through their life-cycle, assuring that IT plans support Center business planning and mission objectives in support of the Family Smoking Prevention and Tobacco Control Act. The Electronic Submissions and Business Automation investment provides development, modernization, and enhancement, as well as operations and maintenance activities, associated with critical core business processes including: internal workflow management, product review and approval, and compliance oversight business requirements.

The Electronic Submissions and Business Automation investment is comprised of four major projects. The first is Business Process Automation (BPA) which automates current business processes being performed manually in order to improve efficiency and ensure compliance with large workloads. The second is Electronic Submissions (CTP eSub) which handles the receipt, review, and response process for tobacco industry electronic and non-electronic submissions. The third is the Tobacco Inspection Management System (TIMS), an iPhone-based mobile application that provides the capability for state inspectors to efficiently and effectively conduct compliance check inspections of retail establishments. The fourth is the Stakeholder Relationship Management System (SRMS) which will enable CTP to manage and leverage new and existing relationships between the offices, as well as with their respective stakeholder communities, to enhance collaboration and information sharing to address stakeholders with consistency and a unified voice.

Funding History Table with FTE Totals

The following table displays funding and full time equivalent (FTE) program levels from FY 2010 through FY 2013, plus FY 2014 request.

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
2010 Actual	$64,418.000	$0	$64,418,000	90
2011 Actual	$135,708,000	$0	$135,708,000	236
2012 Actual	$277,136,000	$0	$277,136,000	379
2013 CR	$457,534,000	$0	$457,534,000	523
2014 Request	$501,476,000	$0	$501,476,000	640

Summary of the Budget Request

The FY 2014 budget request for the Tobacco Control Act Program is $501,476,000. This amount is an increase of $46,725,000 above the FY 2012 Enacted level. The CTP amount is $486,487,000 which supports 570 FTE. The Field amount is $14,989,000 which supports 70 FTE. The source of funding for the request is tobacco user fees. The Tobacco Control Act requires that these user fees may only be used for FDA tobacco regulatory activities. Conversely, the law prohibits the use of non-tobacco funds for FDA tobacco regulatory activities.

The FY 2014 budget allows the Tobacco Control Act Program to protect and promote public health by planning, managing, directing, and coordinating major tobacco program objectives to support the implementation of the Tobacco Control Act.

Reducing Youth Initiation to Tobacco

Center Activities (FY 2012 Enacted Amount: $272,348,000)
FY 2014 increase above the base: +$9,282,000; 137 FTE

In FY 2014, FDA will continue its implementation of the Tobacco Retail Inspection Program. This work includes re-awarding contracts to U.S. States and Territories that are already under contract with FDA to conduct compliance check inspections of retail establishments that sell regulated tobacco products. Efforts will be made to expand the contracts with U.S. States and Territories to cover more retailer inspections, where feasible.

Additionally, FDA will continue to update and enhance its mobile device inspection tool using customized software known as the Tobacco Inspection Management Systems (TIMS) Mobile Application. The tool can help reduce the amount of equipment inspectors need, reduce or eliminate the need to mail, fax, or scan paper forms to and from field inspectors, and reduce data entry, thereby decreasing the time for conducting and reviewing inspections and gathering evidence.

In FY 2014, FDA will continue the expansion of its tobacco-related Promotion, Advertising, and Labeling Enforcement programmatic activities. FDA will enforce the warning label requirements, which includes the review of warning plans for smokeless tobacco products. FDA expects these reviews to increase once the cigarette warnings take effect and when “other tobacco products” are deemed to be subject to Chapter IX of the FD&C Act. FDA will review additional regulatory submissions and applications that contain packaging, labeling or advertising materials.

FDA will continue to conduct monitoring activities, which include reviews of websites, magazines and other publications that promote and sell regulated tobacco products in the U.S. FDA will collaborate with other agencies to ensure that enforcement efforts are coordinated. This effort will require FDA to invest in more advanced information

technologies, including software programs and/or contract for services, to broaden its monitoring and surveillance programs. Consistent with the HHS Strategic Plan and the Secretary's strategic initiatives, FDA will seek to prevent and reduce tobacco use while leveraging systems and resources.

In FY 2014, FDA will continue expansion of its Enforcement and Manufacturing activities by monitoring compliance with registration and listing requirements. FDA will continue to coordinate the activities surrounding the development of Tobacco Product Manufacturing Practice (TPMP) requirements for regulated tobacco manufacturers. As part of the ongoing oversight of these establishments, FDA will continue to develop new mobile technologies to assist in streamlining the efficiency of these inspections.

FDA will continue to provide training, educational webinars and other web-based training for small tobacco product businesses. FDA will also continue to provide information to industry and retailers to ensure a better understanding of the Tobacco Control Act and regulations through the Compliance and Enforcement webpage, compliance training webinars, and by responding to inquiries. FDA will also provide compliance training and outreach to other federal, state and local stakeholders involved in tobacco control.

In FY 2014, FDA will continue to educate the public about tobacco products and their harms. FDA intends to develop public health education campaigns and key messages, support effective design, development, implementation and evaluation of its public health education efforts, and increase the impact of FDA's health education program with FDA's stakeholders and audiences on priority issues and key messages related to FDA tobacco product regulations.

In FY 2014, FDA plans to engage in several major research activities regarding decreasing youth tobacco use initiation. This research will expand the scientific evidence needed to support several authorities in the Tobacco Control Act, and also help assess the impact of regulatory actions on preventing the initiation of tobacco use.

Some of the major research activities planned for FY 2014 includes:

- The Population Assessment of Tobacco and Health (PATH) study, which will support an on-going, national, longitudinal, cohort study of almost 59,000 users and non-users of tobacco products and those at risk for tobacco use ages 12 and older. Research topics in the PATH study related to reducing youth tobacco initiation include understanding what makes people susceptible to tobacco use, evaluating patterns of tobacco product use, and evaluating the effects of regulatory changes on risk perceptions and other tobacco-related attitudes and behaviors.
- The National Youth Tobacco Survey is a nationally-representative cross-sectional survey of middle and high school youth examining tobacco-related beliefs, attitudes, and behaviors, as well as measuring exposure to pro- and anti-tobacco influences. The target sample size is over 24,000 students and the survey will explore a broad range of topics such as use of cigarettes, smokeless tobacco, cigars, pipes, bidis, and

kreteks, as well as newer tobacco products, media and advertising; access to tobacco products and enforcement of restrictions on product access in youth. Because the NYTS is an on-going study, data collected allows FDA to monitor changes in use, knowledge and attitudes over time which provides the agency with an indicator of its effectiveness.

- FDA will work with the National Institutes of Health (NIH) to stimulate investigator-initiated research and release targeted Funding Opportunity Announcements to examine the impact of marketing, communications, use behavior, perceptions, knowledge, attitudes, and beliefs regarding tobacco products and use.
- FDA will target research needs regarding youth tobacco initiation. Examples include Poison Control Center data to understand childhood accidental poisonings from using tobacco products, collection of qualitative and quantitative data to understand how youth and adolescents perceive various tobacco products and understand communications from FDA, and statistical analyses of data sets that will provide information related to youth tobacco use.

Field Activities (FY 2012 Enacted Amount: $6,250,000)
FY 2014 increase above the base: +$8,739,000; 37 FTE

ORA will continue to conduct surveillance, investigations, inspections, sample collections, and other regulatory actions to ensure compliance by manufacturers, distributors, and importers of tobacco products with the requirements of the FD&C Act. By the end of FY 2014, ORA expects to continue conducting biennial tobacco inspections of all registered tobacco manufacturing facilities as required under Section 905(g) of the FD&C Act. ORA in conjunction with CTP will continue efforts to develop and present training to ORA staff.

ORA will continue establishing its testing laboratory at SRL with expertise and capacity to analyze tobacco products. After successful completion and validation of multi-residue flavors methods, ORA will focus on establishing methods to perform product qualification. In addition to analyzing the tobacco product itself, ORA also plans to perform testing on tobacco smoke.

ORA's FCC laboratory continues to provide support to OCI related to identifying criminal violations in tobacco-related cases, as OCI conducts investigations of potential criminal activity. These cases could include counterfeit identification and country of origin determinations. As both SRL and FCC may be using similar analytical tools to address different needs, both labs will be communicating and collaborating on development and use of new methods.

Lastly, ORA will collaborate with CTP regarding the use and enhancement of database and software systems managed by ORA for inspection data, recalls, imported product, enforcement actions, and training purposes. In addition, CTP plans to provide ORA inspectors with new mobile technology to use for their inspections of tobacco product manufacturers.

Reducing Tobacco Product Harms

Center Activities (FY 2012 Enacted Amount: $94,358,000)
FY 2014 increase above the base: $11,230,000; 51 FTE

Even as FDA is trying to educate youth about the dangers of tobacco use, it recognizes that millions of adults currently use tobacco products. FDA is dedicated to helping all tobacco users by working to decrease the harms and addiction caused by use of tobacco products.

In FY 2014, FDA intends to:

- Support scientific research including identifying substances other than nicotine that contribute to tobacco product addiction as well as threshold levels of substances, including nicotine, that generate and sustain addiction
- Identify population measures of addiction
- Consider fast-track of new product and/or modified risk application reviews for significantly less harmful / less addictive tobacco products if this can be scientifically proven by criteria established in the Tobacco Control Act and articulated in published FDA guidance
- Draft guidance to industry and regulation to provide requirements appropriate for each type of premarket submission and review program
- Continue proactive communication processes with industry and the public about the FDA tobacco premarket review process and status of submissions, and
- Conduct and support research to continue to enhance the evidence base for reviewing and making decisions on tobacco industry submissions and to inform regulatory options.

Additional research projects proposed to be funded during FY 2014 will identify the impact of nicotine reduction in tobacco products. These projects are designed to:

- Identify the nicotine concentration below which tobacco products will not be addictive
- Assess the effects of prolonged use of very low nicotine content cigarettes with a particular interest on identifying the differences between abrupt reduction of nicotine versus a gradual reduction
- Examine the acceptability of reduced nicotine products in smokers with schizophrenia, a population with extremely high rates of smoking, and
- Assess the reinforcing effects of nicotine within the context of other components of cigarette smoke.

FDA will also support additional research assessing the toxicity of complex mixtures of tobacco and smoke to further understand the toxicity of individual tobacco constituents. This research will be used to assess toxicity levels of tobacco smoke condensates and to develop genetic toxicological assays.

The foundation of science upon which tobacco product regulation is being built will continue to expand in FY 2014. Data from the PATH study will be used to support FDA's goal to reduce tobacco harms. This longitudinal study will also provide a valuable platform for additional scientific investigations to assess and focus FDA regulatory action.

Scientific review of new tobacco products and substantially equivalent (SE) tobacco products is critical to the fulfillment of the FDA objectives to reduce tobacco product harms and protecting the public health. By reviewing new tobacco product and SE submissions, FDA can prevent marketing of new, potentially more harmful tobacco products or products that raise new issues of public health. To accomplish these evaluations, FDA has developed the regulatory framework for scientific and public health review as required by law and as appropriate for each type of premarket submission. For example, FDA issued final guidance to industry on the submission of SE reports on January 6, 2011, a final regulation on exemptions from SE requirements on July 5, 2011, and draft guidance on premarket tobacco application on September 28, 2011. FDA has not yet received any new tobacco product applications and is reviewing SE reports submitted by industry. Additionally, FDA oversight of investigational studies of tobacco products will help ensure that the proposed studies are designed to minimize risk to human subjects. By monitoring adverse events and industry reports, FDA can detect signals of increased tobacco product harms which may need to be addressed by agency action.

As FDA continues to implement the Tobacco Control Act, it is important to convey to regulated industry and other interested parties FDA's expectations and to clarify aspects of regulatory authority. Development of regulation and guidance documents is an important tool to assist in relaying this message.

In 2014 FDA may develop regulations and guidance in three major areas:

- Product Review and Evaluation Policies -- FDA reviews industry reports and applications for new tobacco products and for products with claims of modified risk. As part of the ongoing development, implementation, and improvement of this review program, regulations may be proposed to standardize the format and content of new tobacco product applications and of reports demonstrating substantial equivalence.
- Tobacco Product Monitoring Policies -- Manufacturers are required by statute to submit information to FDA regarding their research activities and the ingredients and constituents in marketed tobacco products. This information is useful for monitoring changes in grandfathered and new products and identifying emerging areas of research and product development. To improve the quality and usefulness of this information, regulations may be published to specify criteria for measurement and reporting the information.
- Tobacco Product Standards -- The statute authorizes FDA to issue standards that are appropriate for the protection of public health. Examples of rulemaking that FDA may begin working on include standards related to the toxicity and/or addictiveness of tobacco products.

Encouraging Cessation

Center Activities (FY 2012 Enacted Amount: $81,795,000)
FY 2014 increase above the base: +$17,475,000; 36 FTE

The Tobacco Control Act and the FD&C Act contain provisions that are intended to prevent false and misleading advertising of tobacco products, namely by addressing the impact that labeling and advertising can have on consumers. Providing consumers with truthful, accurate and non-misleading information, including information on the negative health consequences of tobacco use in product labeling and advertising may encourage users to quit.

Based on its statutory authorities, one of FDA's major goals is to expand science-based public education efforts to encourage cessation among current users of tobacco products. This will be bolstered by increased efforts to prevent false and misleading advertising, which serves to reinforce incorrect assumptions about the safety of tobacco products, and by the expansion of compliance and enforcement efforts.

During FY 2014, FDA will continue to provide education to the public and stakeholders on tobacco products. FDA will also design and evaluate public education campaigns to encourage current tobacco product users to quit. Collectively, the campaign activities will be rigorously evaluated to determine their effectiveness in increasing tobacco use cessation and creating changes in knowledge, beliefs, and attitudes about tobacco products and use.

In FY 2014, FDA will assist grantees in establishing or expanding public health education programs at the community level, in support of current and future FDA tobacco regulations. Community-based programs will educate the public so as to amplify FDA's messages about FDA's tobacco product regulations.

FDA will continue to evaluate false and misleading claims made in the labeling and advertising of regulated tobacco products. This is an important step in ensuring that current tobacco product users do not receive deceptive information from tobacco manufactures and are equipped with candid information to assist them to quit. U.S State and Territorial contractors will conduct compliance check inspections of retailers, and FDA will conduct inspections of tobacco product manufacturers, thus ensuring that claims on cigarette and smokeless tobacco products' labeling and advertising are truthful and not misleading. In addition, FDA will conduct surveillance of the marketing and promotion of regulated tobacco products on the internet, in magazines, and other publications to ensure regulated industry's compliance with the laws.

FDA will continue to ensure that regulated entities comply with the Tobacco Control Act and is implementing regulations through a multi-pronged approach. This includes assuring industry's compliance with the risk provisions of the law through inspections of tobacco product manufacturers, inspections of tobacco product retailers, review of

tobacco product marketing and promotion on the internet, in magazines and other publications, review of labeling and consumer information, review of regulatory submissions, and evaluation of complaints. Periodic compliance training webinars will be held during FY 2014 to assist small tobacco product manufacturers on how to comply with the labeling and advertising provisions of the law as new provisions become effective.

As new products emerge, including those making modified risk claims, FDA is required to evaluate them based on a population health standard that analyzes the impact of that product on both tobacco product users and non-users, including their effect on initiation and cessation of tobacco use.

FDA will expand its research base in order to study issues relevant to scientific standards for evaluation of tobacco products proposed to be marketed with a modified risk claim. Marketing of modified risk tobacco products is authorized under the Tobacco Control Act if FDA determines that such products have the potential to reduce the burden of tobacco-related disease, death, and disability in the United States. Information regarding modified risk claims will be made public so that current tobacco users are aware of new products and product harms.

During FY 2014, FDA will engage in and support numerous research and scientific endeavors not only to expand the scientific evidence needed for several authorities in the Tobacco Control Act, but to also help assess the impact of regulatory actions on tobacco cessation. The major research activities planned for FY 2014 include:

- Research topics in the PATH study related to encouraging tobacco cessation include examining quit attempts, success in quitting and motivations to quit. Data from this study will be used to strengthen FDA's efforts to encourage tobacco product cessation.
- National Adult Tobacco Survey (NATS) – NATS is a nationally representative cross-sectional survey assessing adult tobacco use and quitting, as well as an individual's knowledge, attitudes and beliefs regarding tobacco. This survey plans for yearly data collection and will provide national estimates of tobacco use prevalence among adults, including the use of tobacco products newly introduced onto the market. Because it is an on-going study, data collected allows FDA to monitor changes in use, knowledge and attitudes over time.
- FDA collaboration with NIH to stimulate investigator-initiated research and release targeted Funding Opportunity Announcements to examine the impact of marketing, communications, use behavior, perceptions, and knowledge, attitudes, and beliefs regarding tobacco products and use on tobacco cessation.
- Initiation of a contract to support both quantitative and qualitative research and data collection on tobacco cessation in order to understand how communications consistent with FDA's regulatory authorities influence quit attempts and quitting.

CTP Performance Activity Data (PAD)

The following table lists the CTP Program Activity Data (PAD) over a four year fiscal period.

CTP Workload and Outputs	FY 2012 Actual	FY 2013 Estimate	FY 2014 Budget
Administrative/Management Support			
Workload			
Number of Advisory Committee Meetings	2	4	6
Number of Warning Letters and Civil Money Penalty Actions (CMPs) Issued	4,524	3,500	3,500
Percentage of Tobacco User Fees Collected	99%	99%	99%

FDA Headquarters

The following table displays funding and full time equivalent (FTE) staffing levels for FY 2012 through FY 2014.

FDA Headquarters

(Dollars in thousands)

	FY 2012 Enacted	FY 2012 Actual	FY 2013 [1] CR	FY 2014 Request	+/- FY 2012
Program Level	**$231,666**	**$199,054**	**$259,597**	**$298,067**	**$66,401**
Program Level FTE	**1,022**	**994**	**1,123**	**1,216**	**222**
Budget Authority	**$162,559**	**$153,519**	**$163,554**	**$173,111**	**$10,552**
Center	$162,559	$153,519	$163,554	$173,111	$10,552
Budget Authority FTE	**756**	**718**	**795**	**782**	**64**
User Fees	**$69,107**	**$45,535**	**$96,043**	**$124,956**	**$55,849**
PDUFA	$42,541	$29,074	$43,829	$46,323	$3,782
FTE	195	194	195	202	8
MDUFMA	$5,975	$3,791	$6,012	$6,485	$510
FTE	21	28	28	29	1
ADUFA	$873	$638	$878	$944	$71
FTE	4	4	4	4	0
AGDUFA	$228	$168	$230	$293	$65
FTE	1	1	1	1	0
MQSA	$238	$270	$238	$238	$0
FTE	2	2	2	2	0
Center for Tobacco Products	$15,196	$11,594	$15,289	$19,500	$4,304
FTE	34	47	34	52	5
Voluntary Qualified Importer Program	$0	$0	$0	$0	$0
FTE	0	0	0	0	0
Food Reinspection	$3,395	$0	$3,416	$3,549	$154
FTE	7	0	7	7	7
Food & Feed Recall User Fee	$661	$0	$665	$691	$30
FTE	2	0	2	2	2
GDUFA			$24,196	$23,988	$23,988
FTE			50	70	70
BSUFA			$1,290	$1,321	$1,321
FTE			5	5	5
Food Establishment Registration & Inspection Fee [2]				$4,486	$4,486
FTE				13	13
Food Import User Fee [2]				$9,278	$9,278
FTE				32	32
Medical Product Reinspection [2]				$6,293	$6,293
FTE				10	10
International Courier [2]				$295	$295
FTE				1	1
Cosmetics User Fee [2]				$1,000	$1,000
FTE				3	3
Food Contact Notification User Fee [2]				$272	$272
FTE				1	1
User Fees FTE	**266**	**276**	**328**	**434**	**158**

[1] Spending authority has been adjusted pursuant to PL 112-175, Section 101(c) for the applicable user fee programs.

[2] Proposed user fee.

Following is a list of the Headquarters legal authorities:

The Federal Food Drug and Cosmetic Act* (21 U.S.C. 321-399)
Radiation Control for Health and Safety Act (21 U.S.C. 360hh-360ss)
The Federal Import Milk Act (21 U.S.C. 142-149)
Public Health Service Act (42 U.S.C. 201, *et seq.*)
Foods Additives Amendments of 1958*
Color Additives Amendments of 1960*
Animal Drug Amendments (21 U.S.C. 360b)
Controlled Substances Act (21 U.S.C. 801-830)
The Fair Packaging and Labeling Act (15 U.S.C. 1451-1461)
Safe Drinking Water Act (21 U.S.C. 349)
Saccharin Study and Labeling Act*
Federal Anti-Tampering Act (18 U.S.C. 1365)
Medical Device Amendments of 1976*
Infant Formula Act of 1980*
Drug Enforcement, Education, and Control Act of 1986*
Generic Animal Drug and Patent Term Restoration Act*
Prescription Drug Marketing Act of 1987*
Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 201)
Prescription Drug Amendments of 1992*
Safe Medical Device Amendments of 1992*
Nutrition Labeling and Education Act of 1990*
Dietary Supplement Health and Education Act of 1994*
Animal Medicinal Drug Use Clarification Act of 1994*
Animal Drug Availability Act of 1996*
Food Quality Protection Act of 1996*
Federal Tea Tasters Repeal Act (42 U.S.C. 41)
Safe Drinking Water Act Amendments of 1996 (21 U.S.C. 349)
Food and Drug Administration Modernization Act of 1997*
Antimicrobial Regulation Technical Corrections Act of 1998*
Medical Device User Fee and Modernization Act of 2002*
Public Health Security and Bioterrorism Preparedness and Response Act of 2002*
Animal Drug User Fee Act of 2003 (21 U.S.C. 379j-11 - 379j-12)
Project Bioshield Act of 2004 (21 U.S.C.360bbb-3)
Minor Use and Minor Species Animal Health Act of 2004*
Food Allergy Labeling and Consumer Protection Act of 2004*
Medical Device User Fee Stabilization Act of 2005*
Sanitary Food Transportation Act of 2005*
Dietary Supplement and Nonprescription Drug and Consumer Protection Act (21 U.S.C. 379aa-1)
Food and Drug Administration Amendments Act of 2007*
Protecting Patients and Affordable Care Act of 2010*

* Authorities under this act do not appear in sequence in the U.S. Code (codified as amended in scattered sections of 21 U.S.C.

The Family Smoking Prevention and Tobacco Control Act of 2009 (P.L. 111-31)
The Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333)
FDA Food Safety Modernization Act, Public Law 111-353 (January 4, 2011)
The Food and Drug Administration Safety and Innovation Act, Public Law 112-144 (July 9, 2012
Allocation Method: Direct Federal/Intramural

Program Description and Accomplishments

FDA Headquarters (HQ) provides Agency-wide program direction and administrative services to ensure that FDA's consumer and patient safety programs are effectively and efficiently managed. Below are the seven primary HQ components responsible for providing Agency-level oversight and advice to FDA leadership and programs.

Office of the Commissioner
Office of Chief Counsel
Office of the Chief Scientist
Office of Foods and Veterinary Medicine
Office of Medical Products and Tobacco
Office of Operations
Office of Global Regulatory Operations and Policy

Office of the Commissioner (OC)
FY 2012 Enacted: $63,353,126 (BA: $49,635,000/ UF, $13, 718,126)

Public Health Focus

OC provides program direction, coordination and liaison, and expert advice to FDA leadership and programs in support of FDA's foods, medical products and science-based work. OC also provides advice and leadership in policy development and oversees FDA rulemaking, and serves as the focal point for coordinating FDA strategic, performance and business-process planning and evaluation.

The following offices are under the Office of the Commissioner:

Office of the Counselor to the Commissioner
Office of Legislation
Office of Policy and Planning
Office of External Affairs

Public Health Outcome

Office of the Counselor to the Commissioner (OCTC)

OCTC provides leadership in advocating for and advancing the Commissioner's priorities and developing and managing FDA emergency and crisis management policies and programs.

OCTC also oversees the Office of Policy and Planning, the Office of Legislation, and the Office of External Affairs.

The Office of Crisis Management (OCM), part of OCTC, provides coordination, strategic management and evaluation of FDA's preparedness and response to incidents involving or impacting FDA regulated commodities. OCM also coordinates the planning, execution and evaluation of inter- and intra-agency emergency exercises to strengthen FDA's preparedness to respond to incidents involving FDA regulated products such as the Salmonella Bareilly outbreak in tuna and the multi-state fungal meningitis outbreak in compounded pharmaceuticals.

The Emergency Operations Network Incident Management System (EON IMS) is OCM's primary system for coordinating and strategically managing FDA's incident responses. EON IMS also supports preparedness exercises that include international, Federal, State and local partners and manages data related to FDA's response to incidents involving FDA regulated products.

EON IMS supports several Congressional mandates:

- Bioterrorism Act of 2002
- Food and Drug Administration Amendments Act of 2001
- Food Safety Modernization Act 2010
- Presidential Policy Directive 8- National Preparedness (PPD).

The following are key EON IMS accomplishments in FY 2012:

- Expanded FDA's Geographic Information System (GIS) and used its mapping capabilities to generate geo-coded maps to respond to foodborne illness outbreaks, incidents involving FDA regulated products and natural and man-made disasters, conduct risk analysis and research projects improving FDA's ability to respond quickly and efficiently to protect the public.
- Conducted exercises and after action reviews to assess response capabilities for international and unintentional foodborne illness outbreaks , major earthquake and tsunami events, cyber-attacks, radiological dispersal device response and a foreign tularemia attack requiring U.S medical countermeasures. FDA increased its participation in emergency exercises by 33%, reflecting the Administration's concerns for several types of significant public health threats.

- Revised the *FDA Emergency Operations Plan* (FDA EOP), an all-discipline, all-hazards plan that establishes a single comprehensive framework for the FDA's management of incidents. The plan is now aligned with national level mandates and guidelines and clarifies the mechanisms for direction and coordination of FDA resources before, during and after emergencies.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
292201: Improve FDA's ability to respond quickly and efficiently to crises and emergencies that involve FDA regulated products. *(Output)*	Implemented electronic notifications of Report-able Food Registry Reports to Federal and State Counterparts. In addition OCM conducted training for FDA staff on the implementation of the FDA Emergency Operations Plan and its incident specific annexes. Progress was made on enhancing interoperability of EON IMS, but delays in funding prevented us from fully expanding its interoperability to systems administered by other agencies. (Target Not Met)	Enhanced FDA's preparedness capabilities by increasing participation in intra/interagency exercises by 25%. Emphasized evaluation of FDA responses to incidents and exercises by establishing a formal evaluation program which will include mandatory comprehensive lessons learned and after action reporting. Enhance interoperability of EON IMS with other systems including those administered by other agencies and expand GIS capabilities to an enterprise-wide approach to provide a wider level of access across the Agency.	Improve the efficiency of agency incident management by expanding responsibility for entering and maintaining incidents in the FDA Emergency Operations Network Incident Management System to include 60% of FDA Regional and 40% of District Offices. Expand access to the agency's Geographical Information System (GIS) through a web-based portal and provide basic spatial analysis tools agency-wide. International exercise to assess effectiveness of FDA and foreign agencies' plans in guiding international response to an intentional product contamination event.	Maintain

Office of Legislation (OL)

The Office of Legislation (OL) directs and manages FDA's legislative needs and Congressional relations. Activities include working with FDA experts and Congressional staff to ensure timely reauthorization of critical programs and review of legislative

proposals, and providing Congress with timely information on FDA public health programs, policies, and initiatives.

In FY 2012, OL worked with FDA officials and Congressional staffs on a number of initiatives and key legislative proposals including the FDA Safety and Innovation Act (FDASIA) of 2012. In FY 2013, OL will continue to educate Members of Congress and staff on key FDA initiatives, such as the reauthorization of the Animal Drug User Fee Act (ADUFA) and the Animal Generic Drug User Fee Act (AGDUFA).

Office of Policy and Planning (OPP)

The Office of Policy and Planning (OPP) advises the Commissioner, other key FDA officials, and FDA Centers and Offices on strategic direction, policy, planning, and evaluation activities that support FDA's public health mission. OPP also supports FDA's key public health work, such as implementation of the Food Safety Modernization Act (FSMA) and the Food and Drug Administration Safety and Innovation Act (FDASIA).

The following provides further explanation of OPP's functions:

- OPP is the policy lead for the Office of the Commissioner on issues that cut across different Centers, as well as serving as the lead on special projects. FDA achieves its public health outcomes in part by issuing regulations, guidance, and other Federal Register documents. The Office of Policy within OPP supports this work by serving as FDA's focal point for regulation and guidance development, coordination, and review, including HHS and inter-Agency review. OP also coordinates publication and review of all FDA rules and notices in the Federal Register and maintains the Unified Agenda.
- The Office of Planning within OPP supports FDA's public health mission by helping develop strategic priorities and measures of performance and evaluating programs to assess their efficacy in meeting program goals. The Planning staff supports FDA's efficiency and effectiveness in several ways, including FDA-TRACK, FDA's agency-wide program performance management system. This assessment process monitors over 110 program offices through several hundred performance measures and projects that are reviewed by FDA senior leadership quarterly and are available to the public through the FDA-TRACK website.
- The Office of Planning's economic analyses of regulations inform policy choices about how efficiently FDA can achieve its public health goals. The Office of Planning's evaluations of and reports on FDA programs, such as the FDA's performance under the prescription drug, medical device, and animal drug user fee acts, assure efficient use of both budget authority and user fee resources.

OPP is leading several efforts to improve the internal coordination, collaboration, and efficiency of agency-wide processes. Among those efforts is a cross-Agency steering committee that is coordinating implementation of FDASIA. OPP also is heading

several strategic planning efforts, including a revision of the FDA Strategic Priorities document to align with revisions to the HHS Strategic Plan that are required under the Government Performance and Results Modernization Act.

Office of External Affairs (OEA)

OEA advises the Commissioner and other key FDA officials on FDA's communications to the media, other stakeholders and the general public on issues that affect FDA-wide programs, projects, strategies, partnerships and initiatives. OEA also serves as a liaison between FDA and the media, consumers, health professional and patient advocacy organizations. OEA consists of four subordinate offices: Office of Media Affairs (OMA) Web and Digital Media Staff (WEB) Office of Communications (OEA/OC) Office of Health and Constituent Affairs (OHCA).

OMA is the principal point of contact for FDA with the news media and is responsible for informing the public about FDA's activities and policies.

OMA accomplished the following activities in FY 2012:

- Issued nearly 200 press announcements, arranged dozens of media events, responded to media inquiries on a daily basis, including coordinating media interviews with agency officials, provided media relations advice to agency officials about newsworthy and controversial issues, and staffed all FDA Congressional hearings, advisory committee meetings and public hearings.
- For FY 2013, OMA plans to continue to issue press announcements about FDA actions and translate communication material, arrange media events, interact with the news media in responding to media inquiries, coordinate media interviews with agency officials, provide media relations advice to agency officials about newsworthy and controversial issues, and staff FDA Congressional hearings, advisory committee meetings and public hearings. In addition, we intend to provide media training services for up to 45 employees.

Web and Digital Media are charged with the following responsibilities in support of FDA's mission:

The FDA Web site (www.FDA.gov) is the fastest, easiest, and most cost-effective communication channel for both FDA and customers and receives more than 20 million visitors each month. Through several OEA-led web improvement projects over the last year, the overall customer satisfaction with the site has increased significantly. The projects have focused on improving search, navigation, and content. FDA uses the American Customer Satisfaction Index (ACSI) to receive feedback directly from our Web site users on their satisfaction with the site. We receive approximately 800 completed

surveys each month. This information is used to provide FDA with an overall customer satisfaction score based on several individual elements, including search, navigation, content, design, and site performance. Since January 2012, the overall customer satisfaction for FDA.gov has steadily improved from 64 to 72 (December 2012). In addition, the individual satisfaction score for search has improved from 62 to 72. These scores are the highest to date for FDA, and additional work in FY 2013 will build on these accomplishments.

OEA/OC informs and interacts with stakeholders about FDA priorities and initiatives. OC includes the Consumer Health Information Staff, which empowers consumers by creating and delivering credible health information. OC builds and maintains public trust in FDA through transparency, access, and openness. OC also coordinates communications with internal and external audiences throughout FDA.

OEA/OC reached nearly six million people online during FY 2012 with its Consumer Updates containing timely and actionable safety and wellness information.
These updates also provided information on FDA's priorities and initiatives. The staff also expanded its efforts to increase FDA's reach by creating and implementing outreach strategies leveraging internal and external web and social media channels
OEA/OC will also prioritize increasing the reach Consumer Updates and the FDA Voice blog, which provides information for all of FDA's stakeholder groups, in FY 2013.

OHCA serves as a liaison between the FDA and patients, patient advocates, health professionals, consumers, states, federal government, industry and other constituents. OHCA staff encourages and supports active participation of these stakeholders in informing FDA regulatory policy to assure FDA's decisions are based upon a full range of perspectives. OHCA is also responsible for communicating important safety and regulatory information to health professionals and patients. The Office has two primary programs—the Patient Liaison Program and the Health Professional Liaison Program. OHCA hosted three large meetings in FY 2012, the health professional organizations conference, the patient network meeting and the patient representative workshop. The patient network meeting, a new meeting for OHCA, focused on FDA's Working with Patients to Explore Benefit/Risk: Opportunities & Challenges. In addition, OHCA hosted nine new multi-faceted educational programs for patient advocates and health professionals on major FDA public health issues. For FY 2013, OHCA will 1) engage with its stakeholders by hosting the health professional organizations conference, the patient network meeting and the patient representative workshop; 2) host at least four new multi-faceted educational programs for patient advocates and health professionals on major FDA public health issues; and 3) actively engage stakeholders by attending and exhibiting at conferences.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
292301: The number of new multi-faceted educational programs for patient advocates and health professionals on major FDA public health issues. *(Output)*	FY 2011: 4 Target: 3 (Target Exceeded)	4	4	Maintain

Office of the Chief Counsel (OCC)
FY 2012 Enacted: $27,127,403 (BA: $15,862,100/UF $11,265,303)

Public Health Focus

The Office of the Chief Counsel (OCC) provides a broad range of critically important legal services to support FDA's public health mission. OCC provides legal advice and policy guidance on a wide range of highly visible national issues and acts as a liaison to the Department of Justice during active litigation. OCC's goal is to support the strategic goals and initiatives of the Commissioner and FDA by providing high quality legal services, including sound and timely legal advice and counsel. As such, this budget request aims to enable OCC to provide FDA with the highest level of legal services required to effectively achieve and implement FDA's goals and initiatives.

Public Health Outcome

In FY 2012, OCC provided key advice on numerous complex legal issues on the implementation of a variety of new laws, including:

- The extensive changes brought about by the Food and Drug Administration Safety and Innovation Act, the FDA Food Safety Modernization Act, the Food and Drug Administration Amendments Act, and the Family Smoking and Prevention and Tobacco Control Act (TCA),
- Medical product approvals and safety issues
- Food safety and nutrition issues
- Animal health issues
- Public health emergencies.

OCC completed review of nearly 90% of over 7,000 requests for legal services within the prescribed timeframes in FY 2012.

OCC also conducts defensive and enforcement litigation, which is critical to protect the public health and ensure that FDA's policies and decisions are implemented. OCC defends:

- Legislative and regulatory changes
- Enforcement and product approval decisions, including stem cell regulation (Regenerative Sciences), tobacco regulation (Commonwealth Brands),
- Actions to enforce FDA priorities including food safety (Sunland registration suspension)
- Actions to enforceadministrative detention (Dominguez Foods)
- Approval decisions (AstraZeneca and Ista).

OCC initiates and conducts seizure and injunction cases in Federal court to ensure that the public is not exposed to illegal products, such as drugs manufactured under poor GMP (Ranbaxy) and unapproved devices (Holistic Candlers).

OCC also actively participates in criminal prosecutions. In FY2012, FDA obtained 262 convictions and $4.9 billion in criminal fines. Recent prosecutions include:

- GlaxoSmithKline (off-label promotion of Paxil, Wellbutrin, Advandia, and other prescription drugs)
- Abbott Laboratories (off-label promotion of Depakote)
- Amgen (misbranding of Aranesp, Neulasta, and Enbrel).

Office of the Chief Scientist (OCS)

FY 2012 Enacted: $37,173,266 (BA: $31,544,200/UF $5,629,066)

Public Health Focus

The Office of the Chief Scientist (OCS) provides the strategic FDA-wide leadership, coordination, planning and scientific training needed to support the applied research and the scientific innovation, excellence, integrity, and collaborations essential for FDA to succeed in its public health mission, including keeping our nation safe . OCS also provides FDA leadership for and representation to HHS and the White House for the US Medical Countermeasures initiative (MCMi) of the Public Health and Emergency Countermeasures Enterprise (PHEMCE), working to speed and enhance the medical countermeasure development that is critical in ensuring our nation's preparedness for natural and man-made threats and disasters, including pandemics, and acts of terrorism.

OCS includes four subordinate offices which collaborate to further FDA's regulatory science priorities and capacity:

- Office of Regulatory Science and Innovation
- Office of Counterterrorism and Emerging Threats
- Office of Scientific Integrity
- Office of Scientific Professional Development.

In addition, OCS has responsibility and programmatic oversight of Office of Minority Health, Office of Women's Health and National Center for Toxicological Research.

Public Health Outcome

FY 2014's increase in Advancing Regulatory Science funding will allow FDA to build upon existing partnerships, including with the public and private sector, to enable FDA to use the rich genomic data it is receiving to support innovation in diagnostics and therapeutics, including for personalized medicine and infectious diseases, as well as to identify product contamination and adulteration. This capability will result in faster, more efficient, product development and better patient outcomes and enable the Agency to both better protect the public and speed lifesaving products to market. In addition, the increase will support translation of basic science advances into practical implementation of new toxicology approaches to protect patients and consumers and enhance the ability to detect problems earlier in product development, reducing costs and protecting human subjects. This increase also creates new opportunities to work with behavioral science experts to identify major scientific gaps in FDA's consumer/provider communications approaches and develop new methods to improve communication and understanding of risks and benefits and better enable both consumers' and health care providers' to make informed choices and use products safely.

The Office of Regulatory Science and Innovation (ORSI)

ORSI leads FDA's cross-cutting programs supporting regulatory science and innovation both across FDA and through public private and other partnerships (PPP). ORSI fosters mission-targeted, interdisciplinary research targeted to develop and enhance the tools needed for product evaluation, including safety and efficacy. Through leadership of the Critical Path and Regulatory Science Initiatives, ORSI plays a critical role in facilitating and expanding scientific efforts needed to provide to innovators in industry and academia clear, efficient safe pathways for developing novel products.

With the broad goals of supporting innovation and advancing regulatory science and critical path initiatives, ORSI has:

- Launched collaborative toxicology programs with the University of Washington and Johns Hopkins University, using novel in-vitro models to investigate and better predict drug efficacy and safety.
- Launched collaborative biomarker research programs with New York University School of Medicine for the blood based detection of BRAF and NRAS DNA as biomarkers to better direct new drug treatments in patients with stage III and IV metastatic melanoma and with Stanford University for qualifying studies of biomarkers for neonatal disease.
- Completed year 1 of research and training by the new Centers of Excellence in Regulatory Science and Innovation (CERSIs) – testing new markers and approaches to cancer drug resistance; new gene and pathway models for

autoimmune diseases and vaccine-related adverse events; and developing new approaches for analysis of 1,000 genomes to better understand racial/ethnic/geographic markers that can affect individuals' responses to drugs. These efforts offer the potential to enable 'precision medicine' approaches that enhance drug safety and effectiveness for diverse populations.

- Developed the Scientific Computing Enclave as a computing environment designed to enable secure data-sharing and collaboration both among FDA scientists and with external researchers, including other HHS components and private sector and academic collaborators.
- Implemented FDA's first Broad Agency Announcement (BAA), which provides a new platform for targeted participation by science and technology- based firms and educational institutions in meeting key needs for advancing regulatory science and innovation.
- Organized FDA's first participation in the USA Science and Engineering Festival. This provided an opportunity to engage elementary and high school students and stimulate the awareness of and interest in FDA science and career opportunities.

ORSI will continue to build on the foundation of science-based initiatives to drive innovation and modernize the sciences supporting the development, evaluation, manufacturing and use of FDA-regulated products. ORSI will continue to support and advance major scientific initiatives such as personalized medicine, innovative clinical trials design strategies and advanced scientific computing in support of the goals of Critical Path and Advancing Regulatory Science, and further broaden its efforts, including through the CERSIs, to enhance FDA collaborations with scientific experts in academia, industry and other governmental agencies.

Office of Counterterrorism and Emerging Threats (OCET)

OCET provides leadership, coordination, and oversight for FDA's counterterrorism and emerging threats (e.g., pandemic influenza) initiatives, including relevant policy, planning and preparedness and response activities. In close coordination with FDA's Centers, OCET develops and implements FDA policies to foster the development and availability of safe, effective medical countermeasures (MCMs)—such as vaccines, drugs, personal protective equipment, and diagnostic tests—needed to counter chemical, biological, radiological, nuclear (CBRN) and other threats. OCET coordinates and facilitates FDA's work with Federal partners through the HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) to build and sustain the MCM programs necessary to prepare for and respond to public health emergencies. OCET also provides overall strategic leadership, coordination, and oversight for FDA's Medical Countermeasures initiative (MCMi). MCMi is an Agency-wide effort to promote the development and availability of MCMs by: (1) enhancing the regulatory review process; (2) advancing regulatory science for MCM development; and (3) modernizing legal, regulatory, and policy frameworks to facilitate MCM development, and access, as well as to ensure an effective public health response.

Recent achievements in facilitating the development and availability of MCMs include:

- Approving important new products, including the antibiotic levofloxacin (Levaquin) to prevent and treat plague, and a monoclonal antibody (Raxibacumab) to prevent and treat inhalational anthrax – both approved for adults and children (the latter the first new therapeutic to be approved under the Animal Rule); approving the first influenza vaccine licensed in the United States produced using modern cell culture techniques (Flucelvax) and the first influenza vaccine to cover four influenza strains (Fluarix Quadrivalent) for adults and pediatrics; and a next-generation highly portable ventilator (AURA Family of Ventilators)
- Establishing innovative regulatory pathways for next-generation smallpox vaccines, smallpox drugs, and multiplex diagnostic tests that enable rapid and simultaneous detection of multiple pathogens

FDA plans for facilitating the development and availability of MCMs in FY 13 include:

- Issuing revised draft guidance to clarify pathways and facilitate product development under the Animal Rule
- Continuing to bring to bring all available expertise to bear on MCM development and evaluation, including through support of both FDA and competitively funded external and collaborative regulatory science research, and engaging the external community through workshops and meetings.

The Office of Scientific Integrity (OSI)

OSI is essential in protecting and promoting FDA's public health mission by strengthening and supporting the integrity and credibility of the Agency's science and science-based decision-making. OSI helps ensure the legitimacy and validity of FDA's research; fairly and comprehensively considers and addresses formal and informal internal disputes and external complaints about Agency decision-making; and develops and implements policies and programs to foster a culture of scientific integrity within the Agency.

The following are key accomplishments for FY 2012:

- Published an FDA-wide policy for the investigation of potential research misconduct (http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/ucm299479.htm) and an overview of Agency scientific integrity policies (http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/ucm289975.htm);
- Coordinated issuance of the Commissioner's decision revoking the Agency's accelerated approval of the breast cancer indication for Avastin (bevacizumab) (http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm279485.htm).

In FY 2013 OSI plans to:

- Strengthen processes and develop new tools for review and oversight of FDA's research involving human subjects, including implementation of new study protocol tracking software to ensure quality, efficiency, and timeliness of agency IRB review; and
- Develop best practices for consideration and resolution of scientific disputes within the Agency (including when multiple FDA components are involved) by learning from the process of resolving past scientific disputes.

Office of Scientific Professional Development (OSPD)

OSPD provides leadership and support for Agency efforts to enhance the scientific and technical expertise and professional development of FDA scientists. OSPD also manages the Commissioner's Fellowship Program; FDA's unique two-year fellowship that provides opportunities for health professionals and scientists to receive training and experience at FDA, and the Interagency Oncology Task Force Fellowship Program, a joint Fellowship with the National Cancer Institute at the National Institutes of Health.

Recent achievements in enhancing FDA staff's scientific professional development opportunities include:

- Graduating the third class of the Commissioner's Fellowship Program with 80% of these graduates remaining at FDA
- Launching the New Frontiers in Science Lectureship Program in collaboration with Health Research Alliance to support FDA's regulatory science training needs
- Implementing the FDA-University of Maryland Center of Excellence in Regulatory Science Lecture Series to support staff regulatory science training needs
- Increasing continuing medical, nursing, and pharmacy educational opportunities including through external partnerships
- Supporting FDA-wide training in the priority areas of Nanotechnology and Medical Countermeasures

Plans for FY 2013 include:

- Coordinating the Commissioner's Fellowship Program, including for graduates and recruiting the next class of Fellows;
- Increasing the number of professional development opportunities for FDA staff, including through personnel exchanges with academia, and increased access to continuing clinical activities for qualified FDA health professionals
- Supporting FDA-wide training programs for Regulatory Science and Medical Countermeasures and for emerging technologies.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Office of Regulatory Science and Innovation (ORSI)

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
293206: Promote innovation and predictability in the development of safe and effective nanotechnology- based products by establishing scientific standards and evaluation frameworks to guide nanotechnology-related regulatory decisions. *(Outcome)*	FY 2012: FDA implemented the Collaborative Opportunities for Research Excellence in Science (CORES) Program to promote cross-center and external collaborative regulatory science research opportunities, focusing on studies evaluating nano-materials. An additional, new component of this activity included inviting external experts to review proposals (Target Met)	Continue regulatory science studies on evaluating nanomaterials from 2011.	Maintain FDA Nanotechnology CORES Program	Maintain

Office of Scientific Professional Development (OSPD)

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
291101: Percentage of Fellows retained at FDA after completing the Fellowship program. *(Outcome)*	FY 2012: 69% Target: 50% (Target Exceeded)	50%	50%	Maintain

Office of Women's Health (OWH)

Public Health Focus

The OWH provides leadership and policy direction for FDA on scientific, ethical and policy issues and ensures that FDA regulatory and oversight functions are responsive to women's health needs. OWH is responsible for activities related to the participation of women in clinical studies (tracking and data analysis) and the creation of novel consumer

health materials pertinent to FDA regulated products. OWH provides grants for applied regulatory research, develops focus-group tested consumer health information in English and Spanish, and facilitates dissemination of information to the public through national award-winning partnerships.

Public Health Outcome

In alignment with Congressional priorities, OWH promotes the inclusion of historically under-represented populations in clinical trials. OWH ensures that Investigational New Drug submission and New Drug Application (NDA) clinical data are broken out by age, race, and sex. In addition, OWH ensures that NDAs include summaries of effectiveness and safety data for important demographic subgroups for age, race and sex.

The Office structure and activities have evolved to meet the needs and priorities of the Agency as well as the needs of our constituents. As a result, OWH strongly embraces change, promotes innovative scientific and educational collaborations, works with FDA centers/offices, government agencies, and national organizations to advance the health of women and their families. Effective strategic thinking and flexibility have allowed OWH to thrive and remain influential and impactful.

Outlined below are 3 Phases developed by the Office to identify activities to fulfill distinct responsibilities and to meet Agency Reporting requirements. These activities outlined create a roadmap to increase internal and external collaborations; improve internal and external communications; increase advocacy; and increase impact results of OWH.

Phase I: Remove Barriers and Advocate for Regulatory Research (within FDA)

- Evaluated the adequacy of current FDA policies and advocated for removal of barriers to the inclusion of women in clinical trials
- Established internal grants programs to support basic women's health research
- Established an internal FDA women's health steering committee

Phase II: Expand Regulatory Research and Communicate with Stakeholders (inside & outside of FDA)

- Worked towards the development of systems for tracking clinical trial demographic data for significant sex differences
- Established "Take Time To Care" outreach activities to develop and disseminate FDA health tested, easy-to-read education materials through national information campaigns in multiple languages
- Established the first disease specific website for the Diabetes Campaign with NACDS and ADA which included information from all HHS public health agencies

- Served as an Agency interface facilitating meetings and dialogues with outside agencies and organizations particularly related to controversial topics
- Increased funding for intramural grants that address gaps in knowledge or that will focus attention on issues that disproportionately affect women
- Multiplied partnerships to facilitate distribution of OWH FDA materials to the public with attention to underserved populations and communities
- Informed stakeholders, using an OWH extensive contacts database, about Agency actions such as new product approvals, safety communications and recall announcements
- Provided training, funding and tools for FDA Public Affairs Specialists consumer outreach activities

Phase III: Creating An Institutional Framework For FDA Collaborative Science (all levels)

- Inform FDA regulatory policy development through increased publications, presentations, hosting scientific dialogues (internal and external) on identified gaps in women's health research. (e.g. OWH has funded more than 125 publications in peer-reviewed scientific journals)
- Create on-line repositories of key product information for use by health professionals and consumers (e.g. pregnancy registries, device videos, etc.)
- Train external health care providers about the importance women's health, consumer needs, and effective communication via online CE training (e.g. starting with our colleges of pharmacy agreement)
- Developing a virtual community of national organizations who blog, "tweet", and broadcast FDA science-based information
- Networking with long-term, loyal partners/constituents (other Federal Agencies, Advocacy, Health Associations, Colleges, Pharmacies, etc) in a web campaign "Come to FDA"
- Expand portfolio of FDA health information through development of consumer non-print/electronic and social media (e.g. infotainment, digital storytelling, virtual communities) for use by healthcare organizations, caregivers, and other HHS agencies
- Provide expert consultation and on-going technical assistance to the FDA centers/offices in the area of consumer communications (e.g. letters, product labeling, planned roll-outs) around controversial topics
- Advance FDA's public health agenda/integrate science base through collaborations and interagency agreements with HRSA, SMSHA, CMS, and NCI
- Seek membership on select FDA Review Committees to be a voice for women and minorities when products are presented for approval (ex. Rogaine, gout, mammography)

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
294201: Number of site visits of Office of Women's Health-funded investigators (multiple year recipients) conducting laboratory-based research. *(Output)*	FY 2012: 9 Target: 9 (Target Met)	9	10	+1
291303: Number of electronic and print communications disseminated to women's health stakeholders. (Output)	FY 2012: 20 (Historical Actual)	NA *[1]	25	+5

*[1]Performance goal 291303 FY2012 was modified to include new communication methods changing the criteria in which to measure the performance goal in FY12..

Office of Minority Health (OMH)

The FDA Office of Minority Health, mandated under the Affordable Care Act of 2010, advances FDA's public health mission in addressing the reduction of racial and ethnic health disparities and in achieving the highest standard of health for all. OMH programs focus on improving FDA capacity by strengthening the research and evaluation of sub-population data which support reduction of health disparities in populations at greatest risk and by promoting effective communication to health care provider, patient and consumer on issues impacting diverse populations.

In alignment with the HHS Action Plan to Reduce Health Disparities, OMH works to advance scientific knowledge and innovation and to increase the availability of information for marketed products for underrepresented populations.

The following are key accomplishments for FY 2012:

- In response to the FDA Safety and Innovation Act (FDASIA) Section 907 (in partnership with Office of Women's Health), and Section 1138, OMH, is leading the development of a report on inclusion in clinical trials and a communication plan addressing with focus on underrepresented populations, respectively.
- OMH has a highly active program of stakeholder outreach to advocacy, health professional, academic and industry partners. These include speaking engagements, presentations, attendance at meetings and other public forums such as the FDA Blog, a webinar on the Office of Minority Health, the *White House Blogger Town Hall on Minority Health, University of Miami School of Medicine Conference to Eliminate Health Disparities in*

Genomic Medicine and *Commonwealth Fund/Harvard University Fellows in Minority Health Policy Orientation.*

- OMH partnered to raise awareness about advisory committees in health professional organizations, such as the National Medical Association, the American Medical Association, the National Hispanic Medical Association, National Council of Asian Pacific Islander Physicians and the American Native Research Network .OMH has reached over 2000 health professionals via email blast and notifications in health professional newsletters and publications.
- OMH collaborated with the Office of Health and Constituent Affairs in the Health Professional and Patient Networks to ensure its reach is inclusive of racial and ethnic minority populations.
- OMH continues to enhance its website and has also established a formal listserv for increasing outreach to minority stakeholders on FDA related issues.
- The OMH Steering Committee was expanded to include Offices and Centers across the Agency to support awareness of and advance program development in Minority Health activities within FDA.

OMH dedicated FY 2012 to building its research capacity and partnerships on its priority areas of HIV/AIDS, diabetes, obesity, aging, tobacco and genomics. Below is a summary of the agreements initiated this fiscal year:

- Through the Office of the Chief Scientist, OMH is collaborating with the Centers of Excellence in Regulatory Science and Innovation (CERSIs), University of Maryland and Georgetown University.
- In collaboration with the Office of Media Affairs, OMH is supporting the expansion of the National Alliance for Hispanic Health's Proyecto Informar program for inclusion of the "Genes, Culture, and Health" project. The project expansion responds to the need for information on epigenomics and personalized medicine and the impact on subpopulations.
- OMH entered Memoranda of Understanding (MOUs) with academic institutions and non-profits with expertise in health disparities. These are Meharry Medical College, University of Hawaii Hilo, University of Hawaii Manoa, and University of Nebraska Medical Center and the Montague Cobb Institute, and the Joslin Diabetes Center/Harvard University. These MOUs form the basis for development of scientific collaborations, outreach and educational initiatives and intellectual partnerships to address health disparities. The types of initiatives expected from these MOUs include:
- Advancing research in priority health disparity areas through collaborations in regulatory science and health disparities
- Providing opportunities to convene joint meetings for education and research as well as opportunities for FDA staff to serve as adjunct faculty or on advisory boards

- Advancing student education and matriculation into the health and biomedical science professions.
- Currently under the MOUs, there are four FDA OMH Health Disparities/ORISE fellows placed at universities for a year-long research project examining health disparities with a regulatory science focus.

Critical to continuing to strengthen its minority health program, FDA OMH will build on the foundation of FY 2012 in health disparities by furthering innovative programs and collaborations with FDA scientists and academic institutions, and patient and health care provider organizations. Through strategic partnerships, OMH will drive projects in harnessing knowledge in FDA databases and minority populations, address challenges in meaningful inclusion of minorities and new methodologies in clinical trials, seek to advance the promise of genomics and minority populations, and improvements for health literacy and issues of cultural competency and limited English proficiency.

Office of Foods and Veterinary Medicine (OFVM)

FY 2012 Enacted: $17,847,500 (BA: $13,791,500/UF $4,056,000)

The Office of Foods and Veterinary Medicine oversees the following Centers:

Center for Veterinary Medicine (CVM)
Center for Food Safety and Applied Nutrition (CFSAN)

Public Health Focus

The Office of Foods and Veterinary Medicine (OFVM) provides executive leadership and strategic direction to the FDA Foods and Veterinary Medicine (FVM) Programs to protect and promote the health of humans and animals by ensuring the safety of the American food supply, food additives and dietary supplements; as well as, the safety of animal feed and the safety and effectiveness of animal drugs. The FVM Program does this by setting science-based standards for preventing food and feed borne illnesses and ensuring

compliance with these standards; protecting the food and feed supply from intentional contamination; and ensuring that food labels contain reliable information and encouraging product reformulation to allow consumers to make healthy choices and promote well-being.

OFVM is also responsible for leading FDA's efforts in responding to foodborne outbreaks and contamination, and the principle lead of the implementation of the FDA Food Safety Modernization Act of 2011 (FSMA). The FVM Program also promotes and protects the health of humans and animals by regulating the manufacture and distribution of food additives and drugs that will be given to animals.

Public Health Outcome

OFVM provides overall guidance and leadership on cross-cutting resource and strategic management activities for the Foods and Veterinary Medicine Programs through risk based decision making and resource allocation. OFVM ensures that FDA has the scientific and regulatory capacities to protect consumers from unsafe foods and unsafe or ineffective animal drugs. OFVM coordinates all elements of FDA's FVM Program to ensure they have the tools they need to work in a closely integrated fashion to prevent food- and feed borne illness, improve the labeling of the food and feed supply, encourage product reformulation to allow consumers to make healthy choices and promote well-being, and prevent harm from drugs and additives given to animals. OFVM also serves as the lead coordinator for FDA's implementation of FSMA. OFVM uses the FDA *Food and Veterinary Medicine (FVM) Program Strategic Plan* as a framework to guide the implementation of FSMA.

Within OFVM, the Coordinated Outbreak Response and Evaluation (CORE) program is responsible for responding to foodborne outbreaks and contamination incidents. In April 2012, CORE launched an investigation, in coordination with internal FDA partners, CDC and state and local health agencies, to identify the source of illnesses reported in association with the consumption of sushi, sashimi, or similar foods. FDA identified two strains linked to the outbreak, Salmonella (Salmonella Bareilly and Salmonella Nchanga) in the frozen yellow tuna product from India.

FDA performed a Seafood Hazard Analysis and Critical Control Point (HACCP) inspection at the Nakaochi scrape yellowfin tuna manufacturer, Moon Fishery Pvt Ltd. in Aroor, India, and collected samples that were found to be positive for the outbreak strain. As a result of the findings, FDA placed the firm on import alert. FDA continues to monitor the recall to ensure that all products are removed from the marketplace. CORE continues to response to recent outbreaks and contamination incidents such as an outbreak of *Escherichia coli* (*E. coli*) O157:H7 infections linked to organic spinach and spring mix blend supplied by State Garden, Inc. located in Chelsea, Massachusetts and a multistate outbreak of *Salmonella* Bredeney infections linked to peanut butter manufactured by Sunland, Inc.

Office of Medical Products and Tobacco (OMPT)

FY 2012 Enacted: $22,861,017 (BA: $11,540,800/UF $11,320,217)

Public Health Focus

OMPT provides high-level coordination and leadership across the Centers for drug, biologics, medical devices, and tobacco products. While the Centers remain as discrete management entities under their current expert leadership, OMPT will carry out the strategic role with the Centers and oversee FDA's Special Medical programs. OMPT's ability to reach consensus on cross -center jurisdictional issues revolving around tobacco products is early "proof of concept" for the formation of the OMPT Directorate.

Public Health Outcome

Office of Special Medical Programs (OSMP)
OSMP serves as the FDA focal point for special public health programs and initiatives that are cross-cutting and clinical, scientific, and/or regulatory in nature. These programs directly support the HHS goal to *Advance Scientific Knowledge and Innovation* through (1) promoting high standards of scientific integrity and ensuring ethical and responsible research practices, such as human subjects protection, (2) supporting accelerated research efforts for medical products to improve greater access to safe and effective medical products for children and for rare disease populations, and (3) improving pediatric medical product safety. OSMP is uniquely positioned within the agency to standardize policies and practices across the agency consistent with statutes and regulations.

Advisory Committee Oversight and Management Staff (ACOMS) within OSMP:

ACOMS ensures that FDA's advisory committees comply with relevant statutory requirements and applicable regulations including the Federal Advisory Committee Act. ACOMS oversees advisory committee operations for all FDA centers and the Office of the Commissioner. Advisory committees contribute to FDA's mission by obtaining outside, independent, expert advice at open public meetings. Advisory committees address topics such as product approvals, adverse event reporting, product manufacturing, risk communication, and new agency initiatives.

By leveraging state-of-the-art expertise of external advisors, FDA has access to the best possible advice to address emerging public health issues. This enables FDA to assess risk quickly and effectively and make science-based decisions affecting public health and safety. FDA currently has 51 advisory committees and panels with 634 authorized positions. The agency holds approximately 85 meetings per year with the participation of over 1,300 outside experts.

In FY 2012, ACOMS accomplished the following: (1) completed a new intranet website to assist FDA staff in managing operations and policy for FDA advisory committees; (2) increased staffing of advisory committees with expert advisors; and (3) trained FDA staff on the review and assessment of financial interests reported by advisory committee members to enhance the integrity of the advisory committee program. In FY 2013, ACOMS plans to (1) develop guidance for the public on review of financial interests of advisory committee members that may give the appearance of a conflict of interest; (2) launch an electronic system to manage the review and assessment of financial interests reported by advisory committee members; (3) develop and implement strategies on effective recruitment for potential members of advisory committees; and (4) revise guidance and policy on FDA advisory committees to comport with the FDA Safety and Innovations Act of 2012.

Office of Good Clinical Practice within OSMP:

The Office of Good Clinical Practice (OGCP) is the key overarching agency program that helps ensure human subject protection (HSP), reliability of clinical trial data, and regulatory compliance. OGCP prioritizes agency policy for HSP and Bioresearch Monitoring (BIMO) and works with domestic and international partners to harmonize efforts for protecting human research participants.

OGCP is the FDA lead for the development of critical HSP regulations and policies such as enforcement action criteria for inspecting sponsors, monitors, contract research organizations, IRBs, and clinical investigators. OGCP conducts clinical trial (HSP/BIMO) training for FDA Center review staff and field investigators that includes important issues such as vulnerable patient populations and investigator financial disclosure.

Each year, OGCP gives expert counsel to more than 2,000 inquiries from regulated industry, researchers, and patients involved in clinical trials. OGCP posts on its public website the redacted questions and answers. Oftentimes, future guidance and educational outreach efforts are based on these questions.

Accomplishments in FY 2012:

- Final Guidance - *FDA Acceptance of Foreign Clinical Studies Not Conducted Under an IND*. This document clarifies for sponsors and applicants how they can demonstrate compliance with FDA's requirements for acceptance of foreign clinical data.
- Draft Guidance - *IRB Responsibilities Related to Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is Needed.* This guidance helps to determine whether the IRB has established and followed written procedures with respect to reviewing investigator qualifications, the adequacy of the site, and the IND/IDE determination.

- Final Rule – Disqualification of a Clinical Investigator – Under this final rule, an investigator determined to be ineligible to receive a particular investigational product is also deemed to be ineligible to receive any FDA-regulated investigational product.

Accomplishments planned for FY2013 –

- Proposed Rule – *Human Subject Protection; Acceptance of Data from Clinical Studies for Medical Devices.* FDA is amending the medical device regulations to address concerns about the increasing globalization of clinical trials. The rule will update the standards for acceptance of data from domestic and foreign clinical studies to ensure human subject protection and data quality.
- Final Guidance - *Financial Disclosure by Clinical Investigators.* This updated guidance is aimed at strengthening FDA's oversight and review of clinical investigators' financial disclosures.
- Staff Manual Guide (SMG)—*Disqualification of an Institutional Review Board (IRB).* This document provides to FDA staff the procedures to follow for disqualifying an IRB or the parent institution responsible for the formal designation or operation of an IRB.

Office of Combination Products (OCP) within OSMP:

OCP is responsible for classifying a product as a drug, device, biologic, or combination product and assigning the product to a Center (CDER, CBER, or CDRH) for regulation. OCP also is responsible for ensuring timely and effective review of combination products, developing postmarket regulations of combination products, and resolving review disputes.

The purpose of OCP's outreach, rulemakings, and guidance development is to assist the regulated industry to understand how FDA classifies medical products and the regulatory requirements for combination products, and to enable industry to comply with the regulatory and technical requirements for combination products in an efficient, effective manner. This helps to speed up medical product innovation. In addition, OCP coordinates with foreign counterparts both to help them understand our programs and to try to identify ways we can work together internationally to ensure efficient, effective regulation of combination products.

In FY 2012, OCP reviewed 56 requests for designation for filing, and filed, reviewed, and issued 33 classification decisions, all within the 60-day statutory required timeframe. To improve transparency regarding data requirements with external stakeholders, OCP worked with CDRH to revise its web tools to allow stakeholders to search for

combination products that have been cleared or approved by CDRH. At the request of stakeholders, OCP also held several training sessions to educate drug/device manufacturers, especially small businesses and international regulators, on the complexities of combination product regulations.

In FY 2013 OCP expects to issue final regulations and accompanying guidance documents on current good manufacturing practice (cGMP) and postmarket safety reporting for combination products. OCP also plans to issue several other guidance documents, including ones that specify submission requirements for post-market changes to combination products, and technical requirements for glass syringes and for pen, jet, and related injectors. These transparency initiatives are intended to help promote the development of innovative combination products.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
293205: Percentage of requests for Designations processed within the 60 day statutory requirement. *(Output)*	FY 2012: 100% Target: 95% (Target Exceeded)	95%	95%	Maintain

Office of Orphan Products Development (OOPD) within OSMP:

OOPD administers the Orphan Drug Act of 1983, which provides incentives to develop products for rare diseases. Since 1982, the OOPD designation, grants, and outreach programs have promoted and advanced the development of products (drugs, biologics, medical devices, and medical foods) that demonstrate promise for the diagnosis and/or treatment of rare diseases or conditions. These are products necessary to treat a patient population that otherwise would be considered too small for profitable research, development, and marketing. These programs directly support the HHS priority to accelerate scientific advances in lifesaving cures and quality health outcomes.

In FY 2012, OOPD accomplished the following:

- Designated 14 Humanitarian Use Devices (HUDs), which are medical devices that benefit fewer than 4,000 people in the U.S. per year. OOPD also developed a HUD guidance document to help clarify the HUD approval criteria and process.
- Designated 179 orphan drugs. These are drugs for the treatment of rare diseases or disorders that affect fewer than 200,000 persons in the U.S. The designated drugs included potential treatments for many kinds of cancers, sickle cell disease, cystic fibrosis, and pediatric multiple sclerosis.

- Funded 16 new grants for clinical study projects and provided continued support for approximately 55 other ongoing studies (total $15.7 million). These extramural research studies test the safety and efficacy of promising new medical products for rare diseases and conditions through human clinical trials.
- Supported (total $3 million) five Pediatric Device Consortia (PDC) that were established around the country to stimulate pediatric device development. Collectively, they have provided development assistance to more than 200 medical device projects.
- Spoke/participated at 55 orphan drug stakeholder meetings to explain the benefits of OOPD programs. OOPD also conducted training courses for researchers and reviewers, workshops for drug and device sponsors, and presentations to national and international rare disease patient groups.

In FY 2013, OOPD plans to accomplish the following:

- Continue the designation and grants programs described above,
- Redesign the PDC grant program to increase effectiveness,
- Continue the outreach efforts to enhance all stages of the development and approval process for medical products to treat rare disease patients.
- Focus resources on implementation of the relevant rare disease and pediatric provisions of FDASIA, which includes drugs, devices, and biological products. The Office will also lead cross-agency coordination and communication on rare disease initiatives to serve the mission of advancing products for rare disease patients.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
293201: The total number of decisions on applications for promising orphan drug and humanitarian use device designations. *(Output)*	FY 2012: 423 Target: 425 (Target Not Met)	425	425	Maintain
293202: The cumulative number of proposed medical devices provided development assistance by the Pediatric Device Consortia. (O*utput)*	FY 2012: 219 Target: 100 (Target Exceeded)	100	225	+125

Office of Pediatric Therapeutics within OSMP:

The Office of Pediatric Therapeutics (OPT) is mandated by Congress to facilitate pediatric access to innovative, safe and effective products. Key programs include:

the pediatric-focused safety reviews of drugs, biologics, vaccines, and selected pediatric devices, ethics consultation and guidance development to assure that children are only enrolled in clinical studies that are scientifically and ethically sound; scientific analysis of pediatric studies submitted to FDA and partnerships to facilitate product development for difficult to study populations such as neonates and to enhance proper use of extrapolation of data from adults; and international communication to assure that children globally are not exposed to unnecessary or duplicative clinical trials.

In FY 2012, the Office accomplished the following activities:

- Held three Pediatric Advisory Committee (PAC) meetings to address the safety of 42 pediatric medical products. Over 215 pediatric medical products have been reviewed for safety since 2003.
- Provided more than 50 ethics consults to the FDA Centers about pediatric products in order to facilitate pediatric product development.
- Published 15 scientific articles on pediatric products in 2012 (40 in the past 5 years),
- Contributed to the development of 35 pediatric labeling changes in 2012,
- Identified more than 90 pediatric science and ethical issues with pediatric products and took collaborative actions through international efforts with the European Medicines Agency and Latin America,
- Completed developmental milestones regarding the recently initiated Kidnet active surveillance program to enhance the knowledge of pediatric drug and safety concerns in the neonatal and pediatric ICU settings.

In FY 2013, OPT will continue to meet the Congressional requirements (see previous pages) with base resources and address new requirements identified in recent FDASIA legislation. OPT proposes to meet the FDASIA neonatal mandate through a combination of 2 important activities: (1) hire an experienced neonatologist, and (2) establish a neonatal subcommittee of the PAC to advise the Agency on general matters of neonatal issues.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
293203: Number of pediatric scientific and ethical, product and product class issues identified through collaboration with the 27 European Union countries coordinated with the	FY 2012: 99 Target: 36 (Target Exceeded)	36	40	+4

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
EMA, with Japan and Canada as observers, and through separate collaboration with Latin America. *(Output)*				
293204: Number of new medical products studied in children with labeling changes and safety reviews completed. *(Output)*	FY 2012: 42 Target: 40 (Target Exceeded)	40	40	Maintain

Office of Operations (OO)
FY 2012 Enacted: $51,878,334 (BA: $33,601,400/UF $18,276,934)

Public Health Focus

The Office of Operations (OO or the Office) provides executive direction, leadership, coordination, and guidance for the overall day-to-day administrative operations of the FDA ensuring timely and effective implementation and high-quality delivery of services across FDA in support of its mission-critical programs.

The following are some of the client service functions that are coordinated among the subordinate offices in OO:

- Plans, organizes and develops annual and multi-year budget justifications and initiative proposals in support of FDA's public health mission and programs. Plans, directs and coordinates a comprehensive financial management programs for the FDA that encompasses the areas of financial systems, accounting, financial reporting, and acquisitions. (Office of Finance, Budget and Acquisitions)
- Develops and recommends policies and priorities designed to implement the intent of the Office of Personnel Management, Equal Employment Opportunity Commission, Office of Civil Rights, to ensure FDA is inclusive of its diverse workforce. (Office of Equal Employment Opportunity)
- Manages and administers the suitability and security program as required by the Office of Personnel Management as set forth in "Suitability" (5 CFR Part 731), and "National Security Positions" (5 CFR, Part 732). Monitors security clearance levels for Agency positions and FDA employees. (Office of Security Operations)
- Manages programs in occupational medicine, radiation safety, biological safety, environmental compliance and occupational safety. Oversees the operation of five Health Units in the Washington Metropolitan area and a national occupational medicine program. (Employee Safety and Environmental Management Staff)
- Provides support services and executive direction, leadership, coordination and guidance for the operations of FDA (Office of Business Services).

- Provides leadership and guidance to Agency components for all aspects of facilities engineering, and management of the Agency's nationwide real property portfolio. (Office of Facilities Engineering and Mission Support Services)
- Provides advice and assistance to the Commissioner and senior management officials on information management resources and programs. Oversees implementation of the FDA information management policy and policy governance, procedures and processes to ensure compliance with the Clinger Cohen Act. (Office of Information Management)
- Provides human resource guidance on classification, employment and recruitment, workforce policies, and standard operating procedures (Office of Human Resources).

Public Health Outcome

FDA has made accomplishments in using remote technologies and data sharing to help scientists conduct their research. The Agency established FDA's first Institutional Biosafety Committee and trained appropriate personnel for protocol reviews. FDA's Office of Human Resources has established a Human Resource Help Desk and has been working to develop a standardized reporting system to provide the status of personnel actions to customers. Such human resource enhancements help the FDA scientists attain the resources to develop public health solutions. In addition, FDA promoted Strategic Sourcing Initiatives that reduced the number of purchase orders and contracts issued, saving over $10,000,000 in FY 2012.

One of the Office's top priorities is to make continuous improvements for FDA's financial management and information technology systems. The performance goals below provide illustrative examples of OO's accomplishments toward this business priority.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Office of Financial Management

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
291402: FDA's implementation of HHS's Unified Financial Management System (UFMS). *(Efficiency)*	FY 2011: Expanded FDA's reporting capabilities; defined the TO-BE UFMS processes and developed a comprehensive training program. (Target	1) Continue collaborating with the Department in implementing Department-wide its OBIEE business intelligence platform and Hyperion Extension Solutions. Participate in the	Continue supporting the Department (in the different development phases) with the OBIEE and Hyperion expansions and the Data Archiving and	NA

	Met)	Department's Solution for Data Management / Data Archiving and Retrieval System Department-wide. 2) Continue to improve FDA's end-to-end business processes and job aids. 3) Continue development of training courses consistent with the CFO Act. 4) Participate in 4 UFMS Planned Point Releases.	Retrieval System. Continue work to meet requirements to meet Treasury/GSA Mandates – 1) Government-wide Treasury Account Symbol (GTAS) Upgrades, 2) continue development of the UFMS e-Travel Interface to the new Government Travel System. 3) New Intra-Governmental Payment and Collections (IPAC) Enhancements and 4) New Payment Application Modernization-Secure Payment System (PAM/SPS) Payment Format Enhancements. Continue with on going improvements with end-to-end business processes and job aids, training efforts, and support UFMS Point Releases as planned.	

Office of Information Management

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
291405: Percentage of application availability (uptime less non-scheduled emergency outages). *(Output)*	FY 2012: 99.8% Target: 98.5% (Target Exceeded)	98.5%	98.5%	Maintain

In FY 2014, OO will continue to explore and implement innovative approaches to business service delivery to support the Agency's varied programs to ensure the safety of our Nation's food supply and medical products. Additionally, OO/OIM will expend $5 million to implement FDA's Big Data Initiative—transforming processes from being activity-driven to be data driven.

FDA is uniquely positioned to transform and improve multiple aspects of healthcare via the Big Data Initiative that focuses on creating and distributing knowledge that fills in critical gaps to achieving breakthrough progress. FDA has the potential to significantly increase its public health impact by harnessing the richest healthcare data sets in existence.

The Big Data Initiative will focus on the use of structured, unstructured, and high-content data to modernize FDA processes, create usable knowledge for decision support and build new models of healthcare efficacy. These new models will be invaluable in the areas of modernizing the food and medical product inspection process, mining massive data sets that have been compiled at FDA's National Center for Toxicological Research, and improving cancer treatment and decision making.

Office of Global Regulatory Operations and Policy (OGROP)
FY 2012 Enacted: $11,425,354 (BA: $6,584,000/UF $4,841,354)

Public Health Focus

OGROP provides broad direction and support to the Office of International Programs and the Office of Regulatory Affairs. OGROP serves as the Agency's lead for providing strategic leadership, policy direction, and oversight to FDA's global collaborations, data-sharing, development and harmonization of standards, field operations, and risk-based compliance and enforcement activities. OGROP works with agency leaders to enhance FDA's global efforts transforming FDA from being a regulator of domestic products to one overseeing a worldwide enterprise of food and drug production and supply, as well as the science that is the foundation of the products FDA regulates.

Public Health Outcome

The Office of International Programs (OIP) serves as FDA's focal point for all international matters. Office of Regulatory Affairs (ORA) leads all FDA field activities, advising FDA leadership on imports, inspections, and enforcement policies. ORA's resource summaries, Budget Requests, and associated performance measures are found in the Field Activities Narrative

OIP leads, manages, and coordinates all of FDA's international activities, providing high quality information to enable our centers and border officials to make better decisions regarding the quality, safety, and effectiveness of foreign-made products destined for the U.S. market. OIP develops and maintains cooperative relations with international regulatory agencies, industry, as well as other international organizations.

The following are key accomplishments in FY 2012:

- Expanded access of Food Safety Modernization Act (FSMA) and other food safety documents to foreign stakeholders through web-posting of regulatory documents in 11 languages; developed a web-based seminar that reached over 30 countries, and translated educational videos into 6 languages for use throughout the world, partnering with CFSAN.
- Provided substantive support to 8 bilateral meetings with Brazil, the European Union, United Kingdom, Mexico, India, Canada, and China. OIP led the implementation of 3 WHO cooperative agreement awards into one "umbrella" agreement to align with FSMA priorities, streamlining management and efficient reporting strategies, to build knowledge and strengthen food safety and nutrition.
- Led efforts to build global coalitions and strengthen regulatory systems, developed and maintained contact information for experts in drug regulatory agencies in 15 countries, worked with CDER to host an expert circle of the Pharmaceutical Inspection Convention and Cooperation Scheme (PIC/S), to advance medical product safety and effectiveness.
- Engaged with FDA Centers to align strategy for global engagement, developed and negotiated 10 new Confidentiality Commitments and Cooperative Agreements including Chile, Japan, Canada, New Zealand, and Mexico; led efforts to establish a system to track non-public information exchanges with foreign counterparts.
- Built FDA knowledge base for local landscaping globally through development of 16 analytical papers and global bytes across all product categories.
- Participated in TransPacific Partnership negotiations among other international meetings, to champion and protect FDA's equities in international trade.

OIP will address globalization and promote product safety and quality by continuing to build global coalitions of regulators, championing convergent global standards to provide transparency and efficiency, and leveraging resources with an aim toward mutual reliance where feasible. Through enhanced landscaping, intelligence gathering, and sharing information with global regulatory partners, OIP will apply risk analytics to more

rapidly identify product quality and safety problems and support sound regulatory decisions.

Performance Measure

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2014 Target	FY 2014 +/- FY 2012
291304: Number of collaborative actions taken based upon meaningful analyses of the global regulatory landscape. *(Output)*	NA	NA	25	NA

Information Technology Investments – FDA Headquarters Activities (Base Amount displayed as a non-add item: $58,678,771)

The Office of the Commissioner/Headquarters activities include administrative, legal, policy, communications, and scientific support for FDA, as well as activities that more specifically support either the medical product, food safety, or globalization programs. eDepart will build on the success of eArrive, a universal system that streamlined and standardized the entry process throughout FDA for each new FDA employee and contractor, and is anticipated to accomplish the same for employee and contractor exit processes.

The National Antimicrobial Resistance Monitoring System (NARMS) supports the Food Safety Modernization Act in partnership with state and federal stakeholders. The KidNet and Safety Tracking databases provide a platform for pediatric safety. Collaboration between federal, state, and local agencies through the Reportable Food Registry and information-sharing data systems, help identify public health threats. New tools and standards will speed the development of Medical Countermeasures (MCMs). In addition, the Emergency Operations Network (EON) supports the identification and mitigation of public health emergencies related to FDA-regulated products.

Enhanced capability, through FDA-wide enterprise investments is of extreme importance in vaccine safety and mitigating the impact of infectious disease or possible pandemics. Use of internet-based social media tools enable groups to more effectively collaborate on work products, and enhance communication and knowledge management between public, private, and government stakeholders.

IT systems and infrastructure will support and improve efficiency of critical FDA functions and enhance existing operational capabilities to ensure continuity of operations during an

emergency outbreak such as a pandemic influenza outbreak, food and drug recalls and other national emergencies that may affect the public health, as well as the recovery of mission critical IT systems due to man-made or natural disaster affecting the FDA's IT systems.

Five Year Funding Table with FTE Totals

The following table displays funding and full time equivalent (FTE) staff levels from FY 2010 through FY 2014 for FDA Headquarters.

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
FY 2010 Actual	$178,300,000	$141,321,000	$36,979,000	947
FY 2011 Actual	$186,665,000	$149,477,000	$37,188,000	922
FY 2012 Actual	$199,054,000	$153,519,000	$45,535,000	994
FY 2013 CR	$259,597,000	$163,554,000	$96,043,000	1,123
FY 2014 Request	$298,067,000	$173,111,000	$124,956,000	1,216

Summary of Budget Request

The FY 2014 budget request for FDA Headquarters is $298,067,000 supporting 1,216 FTE. This amount is an increase of $66,401,000 above the FY 2012 Enacted level. The source of funding for this request is $173,111,000 in budget authority and $124,956,000 in user fees.

The base funding of $231,666,000 allows FDA Headquarters to provide FDA with program direction and administrative services critical to ensuring that FDA’s consumer protection efforts are managed effectively and efficiently.

The initiatives proposed under the FY 2014 budget request support HHS and Presidential public health priorities and mission-critical program activities to Transform Food Safety and Protect Patients.

Budget Request

Pay Increase

The request for $727,000 in total BA for the FDA Headquarters reflects a pay increase for Civilian and Commissioned Corps staff.

Adjustment to Base

The budget request of $173,111,000 in total budget authority for FDA Headquarters also reflects a reduction to the base of $7,285,000 for FY 2014.

FY 2014 increase for user fees:

PDUFA: $3,782,000 / 8 FTE
MDUFMA: $510,000 / 1 FTE
Tobacco: $4,304,000 / 5 FTE
GDUFA: $23,988,000 / 70 FTE
BSUFA: $1,321,000 / 5 FTE
Food Re-inspection: $154,000 / 7 FTE
Food Recall: $30,000 / 2 FTE

FY 2014 increase for proposed user fees:

ADUFA: $71,000 / 0 FTE
AGDUFA: $65,000 / 0 FTE
Medical Products Re-inspection: $6,293,000 / 10 FTE
International Courier: $295,000 / 1 FTE
Food Establishment Registration Fee: $4,486,000 / 13 FTE
Food Import: $9,278,000 / 32 FTE
Cosmetic User Fees: $1,000,000 / 3 FTE
Food Contact Notification User Fee: $272,000 / 1 FTE

FY 2014 Initiatives:

Food Safety Modernization: Program Support
(+$5,811,000 / 7 FTE)

The FY 2014 Implementing the FSMA initiative includes resources to ensure that programs participating in this initiative receive the support necessary to achieve their public health outcomes. Program support includes activities such as:

- Finance and budgeting
- Human resources support
- Contracting, billing, and legal support
- Communications, ethics, headquarters coordination, and related support functions.

China Foods Initiative:
(+$4,112,500 / 8 FTE)

This FDA investment supports a prevention-focused import safety program in China, which is the source of a large and growing volume of imported foods and food ingredients. This initiative will place greater responsibility on Chinese food manufacturers, processors, packers and distributors to assure that food and food ingredients imported to the United States are safe and meet FDA standards.

With this investment, FDA will perform additional foreign inspections in China, focusing on facilities that produce higher risk foods and food ingredients destined for export to the United States. FDA will also conduct outreach and education activities for Chinese manufacturers on implementing measures to meet FDA food safety, quality and good manufacturing practices.

FDA will expand risk modeling and risk analysis to improve FDA's ability to target inspection resources to high-risk foods and manufacturing that originate in China.

China Foods Initiative: Program Support
(+$262,500)

The Transforming Food Safety Initiative includes resources to ensure that the programs that participate in this initiative receive the support necessary to achieve their outcomes Include:

- Finance and budgeting
- Human resource assistance
- Contracting, billing, and legal counsel
- Communications, ethics, headquarters coordination and related support functions.

China Protecting Patients Initiative:
(+$5,287,500 / 11 FTE)

This FDA investment supports a prevention-focused import safety program in China, which is the source of a large and growing volume of imported drugs and drug ingredients. This initiative will place greater responsibility on Chinese manufacturers to institute measures to assure that drugs and drug ingredients imported to the United States are safe and meet FDA standards.

With this investment, FDA will perform additional foreign inspections in China, focusing on facilities that produce drugs and drug ingredients that pose the greatest risks to patients in the United States. FDA will also conduct outreach and education activities for Chinese manufacturers on implementing measures to meet FDA manufacturing quality and good manufacturing practices.

FDA will also expand risk modeling and risk analysis to improve FDA's ability to target inspection resources to high-risk drugs and drug ingredients manufactured in China.

China Protecting Patients Initiative: Program Support
(+$337,500)

The Protecting Patients Initiative includes resources to ensure that the programs that participate in this initiative receive the support necessary to achieve their outcomes include:

- Finance and budgeting
- Human resource assistance
- Contracting, billing, and legal counsel
- Communications, ethics, headquarters coordination and related support functions.

Advancing Medical Countermeasures Initiative:
(+$1,299,000 / 0 FTE)

The Office of Counterterrorism and Emerging Threats will lead, implement, coordinate, manage, track and report on the activities and outcomes associated with the FDA Public Health and Security Action Plan and each of the 3 objectives of the FDA Medical Countermeasures Initiative. FDA will establish Public Health and Security Action Teams (PHSATs) to support enhanced review of the highest priority medical countermeasures, novel approaches to manufacturing, and related technologies to address the most pressing national security requirements. FDA will establish an MCM regulatory science program and robust scientific collaborations with MCM Enterprise partners, including the Department of Defense. FDA will work collaboratively with HHS to examine the legal framework and the regulatory and policy approaches for MCM development and availability to ensure these adequately support emergency preparedness and response. FDA will develop and sustain educational resources for FDA staff to support the objectives of the Medical Countermeasures Initiative, including a dedicated lecture series and targeted threat briefings for reviewers responsible for medical countermeasures.

Infrastructure
GSA RENT, OTHER RENT AND WHITE OAK CONSOLIDATION

The following table displays funding levels for FY 2012 through FY 2014.

FDA Program Resources Table

(Dollars in thousands)

	FY 2012 Enacted	FY 2012 Actual	FY 2013 CR	FY 2014 Request	+/- FY 2012 Enacted
Program Level	**$337,111**	**$321,259**	**$357,539**	**$410,861**	**$73,750**
GSA Rental Payments	$205,472	$187,655	$210,998	$228,034	$22,562
Other Rent and Rent Related	$87,658	$89,803	$102,239	$120,905	$33,247
FDA White Oak Consolidation	$43,981	$43,801	$44,302	$61,922	$17,941
Budget Authority	**$266,490**	**$266,490**	**$268,120**	**$294,664**	**$28,174**
GSA Rental Payments	$160,506	$160,506	$161,488	$162,014	$1,508
Other Rent and Rent Related	$65,598	$65,598	$65,999	$74,606	$9,008
FDA White Oak Consolidation	$40,386	$40,386	$40,633	$58,044	$17,658
User Fees					
GSA Rental Payments	**$44,966**	**$27,149**	**$49,510**	**$66,020**	**$21,054**
PDUFA	$31,928	$18,742	$21,569	$22,997	($8,931)
MDUFMA	$4,308	$2,347	$4,334	$6,216	$1,908
ADUFA	$1,115	$559	$1,122	$1,180	$65
AGDUFA	$340	$99	$342	$440	$100
Tobacco	$5,503	$5,402	$5,537	$9,974	$4,471
Food Reinspection User Fee	$1,338	$0	$1,346	$1,399	$61
Food and Feed Recall User Fee	$434	$0	$437	$454	$20
Voluntary Qualified Importer Program	$0	$0	$0	$0	$0
GDUFA			$13,815	$14,138	$14,138
BSUFA			$1,008	$1,033	$1,033
Med. Products Reinspection [1]				$1,094	$1,094
International Courier User Fee [1]				$313	$313
Food Establishment Registration & Insp Fee [1]				$1,438	$1,438
Food Import Fee [1]				$4,330	$4,330
Cosmetics User Fee [1]				$900	$900
Food Contact Notification User Fee [1]				$114	$114
Other Rent and Rent Related	**$22,060**	**$24,205**	**$36,240**	**$46,299**	**$24,239**
PDUFA	$17,996	$21,062	$25,130	$26,794	$8,798
MDUFMA	$1,390	$1,470	$1,399	$3,546	$2,156
ADUFA	$204	$76	$205	$236	$32
AGDUFA	$80	$18	$80	$73	($7)
Tobacco	$1,550	$1,579	$1,559	$3,050	$1,500
Food Reinspection User Fee	$592	$0	$595	$619	$27
Food and Feed Recall User Fee	$248	$0	$249	$259	$11
Voluntary Qualified Importer Program	$0	$0	$0	$0	$0
GDUFA			$6,447	$6,598	$6,598
BSUFA			$576	$590	$590
Med. Products Reinspection [1]				$486	$486
International Courier User Fee [1]				$180	$180
Food Establishment Registration & Insp Fee [1]				$811	$811
Food Import Fee [1]				$2,478	$2,478
Cosmetics User Fee [1]				$514	$514
Food Contact Notification User Fee [1]				$65	$65
FDA White Oak Consolidation	**$3,595**	**$3,415**	**$3,669**	**$3,878**	**$283**
PDUFA	$3,595	$3,415	$3,669	$3,878	$283

[1] Proposed User fee; the amount includes associated rent activity.

Spending authority has been adjusted pursuant to PL 112-175, Section 101(c) for the applicable user fee programs.

The following are the legal authorities for GSA Rent and Other Rent and Rent Related activities:

The Public Buildings Act of 1959 (40 USC 601-619)
Public Buildings Act: Public Buildings Amendments of 1972 (P.L. 92-313, 86 Stat. 216)
Public Buildings Cooperative Use Act of 1976 (P.L. 94-541, 90 Stat 2505)
Public Buildings Amendments of 1988 (P.L.100-678, 102 Stat 4049)
The Federal Property and Administrative Services Act of 1949 (40 USC 486[d] and [e])
Omnibus Appropriations Act of 2009 (P.L. 111-8, 123 Stat. 524)
Energy Independence & Security Act of 2007 (P.L. 10-140, 121 Stat. 1492)

The following are the legal authorities to establish and consolidate FDA facilities at the White Oak Campus:

The Food and Drug Administration Revitalization Act (21 U.S.C. 379b)
Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321-399)
Treasury, Postal Service and General Government Appropriations Act (5 U.S.C.)

Allocation Method: Direct Federal/Intramural

Program Description Overview

The Infrastructure Program supports FDA's mission of protecting the nation's public health by providing the FDA Programs with secure and cost-effective office and laboratory space to perform mission critical work. The Infrastructure Program consists of:
General Services Administration (GSA) Rental Payments
Other Rent and Rent-Related Activities
The FDA White Oak Consolidation.

GSA Rental Payments

The GSA Rental account includes FDA rental payments to cover FDA's office and laboratory facilities.

FDA currently occupies 5.9 million square feet of GSA-owned or -leased office, laboratory, and warehouse space. More than two-thirds of the GSA rent charges for GSA-owned or GSA-leased space are for facilities in the Washington, D.C. area. The largest amounts include charges for CFSAN's College Park complex and the White Oak, Maryland Campus, now housing most of FDA Headquarters, CDER, and CDRH. In total, FDA occupies GSA space comprising approximately 290 buildings including District Offices, Regional Offices, laboratories, and resident posts across the nation and in Puerto Rico.

The GSA Rent program continues to conduct numerous activities to ensure that the FDA workforce has the space and security necessary to carry out FDA's mission of protecting the public health in an efficient and effective manner.

In FY 2012, FDA vacated one Headquarters location in Rockville, MD, and relocated the two offices occupying that building to telework hotels that were established in underutilized space in another leased building in Rockville and in a building on the White Oak Campus. FDA also accepted occupancy of a Child Care Center on the White Oak Campus and acquired expansion space in a warehouse facility in Beltsville, MD, near the White Oak Campus.

During FY 2012, FDA's OCI opened one new Field Office and has plans to expand another Field Office. ORA will vacate one Resident Post, acquire expansion space for three Resident Posts, relocate ten Resident Posts, and open four new Resident Posts. ORA will also relocate one District Office and acquire expansion space for six District Offices.

FDA is working with the Department of Health and Human Services (DHHS) to promote maximum utilization of Federal workspace, consistent with mission requirements, and to maximize its value to the Government. FDA strives to be cost effective and energy efficient when it acquires the necessary space to meet the mission and nationally recognized standards.

Other Rent and Rent-Related Activities

The Other Rent and Rent-Related Activities account includes commercial rent and rent-related charges that are not part of the GSA Rent account. These funds cover costs for operating and maintaining FDA and GSA facilities located nationwide. Costs include commercial rent, operation and maintenance contracts, janitorial and grounds maintenance contracts, and above standard security and guard services contract costs. The program also funds standard utilities in FDA owned facilities, essential overtime utilities in laboratories and data centers, and other above-standard level services not provided by GSA in GSA-managed facilities. These accounts directly support the FDA workforce in meeting its public health mission by providing safe, efficient and secure facilities.

FDA is undertaking numerous energy saving projects to decrease long term energy usage and associated operating and maintenance costs while increasing the life span and efficiency of facilities. These efficiencies will help FDA realize significant savings in Other Rent and Rent Related Activities. The implementation of these projects supports Executive Order 13423, Strengthening Federal Environmental, Energy, and Transportation Management, and Executive Order 13514, Federal Leadership in Environmental, Energy, and Economic Performance. These projects contribute to meeting the requirements of DHHS' Efficient Energy Management Assessments, the Energy Policy Act of 2005, the DHHS Sustainable and High Performance Buildings

Policy, HHS Sustainable Buildings Plan, and the 2006 Federal Leadership in High Performance and Sustainable Buildings Memorandum of Understanding.

FDA continues to investigate strategies to save federal funding on overhead while efficiently supporting the FDA mission.

FDA is considering a second energy saving contract for the Muirkirk Road Campus in Laurel, Maryland. Washington Gas and FDA conducted an investment grade audit in March 2011. The estimated capital investment is $2.0 million, with utility cost savings of approximately $252,095 annually in water, sewer, electricity and fuel costs. This change will generate a simple pay back in approximately 7.94 years.

Washington Gas also identified facility improvement measures including electrical upgrades and replacement of the aged switchgear system and HVAC control upgrades. The replacement of this equipment improves the facility condition index.

FDA is also considering a Utility Service Contract (UESC) for the ORA District Laboratory and Office in Irvine, California with the Southern California Edison Electric Power Company. If determined to be cost effective and economically feasible, FDA will proceed with awarding the contract in FY13. Based on the Preliminary Audit, the estimated capital investment is $1.5 million and cost savings will be about $160,000 per year with a simple pay back of 9.4 years.

GSA is currently performing audits in FDA occupied leased facilities, such as the Wiley building in College Park, MD (preliminary audit prepared by Washington Gas dated April 2012 is currently under FDA and FEMP review), and in the Queens, NY, lab. UESCs in these GSA leased buildings will, if implemented, provide energy savings.

Awarding additional UESCs and procuring renewable energy will contribute to DHHS sustainability goals established in the DHHS Strategic Sustainability Plan developed in accordance with Executive Order 13514, Federal Leadership in Environmental, Energy and Economic Performance. More specifically, FDA's activities related to UESCs and renewable energy will help reduce Scope 1 and 3 greenhouse gas emissions.

White Oak

FDA's Headquarters' consolidation to the White Oak Campus is replacing and centralizing existing geographically disparate facilities with new, state-of-the art laboratories, office buildings and support facilities into one location. While the GSA appropriation funds the design and construction of the new buildings at White Oak, FDA's appropriation and PDUFA user fees fund building infrastructure, fit-out, specialized equipment and move costs. FDA initiated relocation activities to White Oak in FY 2002.

The total number of employees currently working on the White Oak Campus is 5,768. Presently, FDA plans to relocate an additional 2,500 employees to the Life Sciences-

Biodefense Complex on the White Oak Campus for a total White Oak population of 8,268 by the end of FY 2014. GSA requested no funding in FY 2013 or FY 2014 for the FDA project. If adequate GSA design and construction funds are appropriated in FY 2015 for the remaining buildings identified in the 2009 Master Plan, FDA plans to relocate approximately 621 employees, for a total on Campus of 8,889 and the current phase of the consolidation will conclude in FY 2018.

Currently completed design plans include:
The Southeast Parking Garage — plans completed in May 2009 but garage has not been funded for construction — will be constructed pending the FY 2015 GSA construction appropriation. The date of completion is to be determined.
Buildings 52/72 and 10 (Vivarium) — Construction ongoing; the Life Sciences-Biodefense Laboratories II and III and the vivarium, and Office Building 71 — to house CBER and CDER staff: Construction began in the fourth quarter of FY 2010, and will be completed by FY 2014.
Building 75 — Construction ongoing; an office and laboratory support facility intended to house CBER, other CDER, and ORA program requirements. Construction began in the fourth quarter of FY 2011, and will be completed by FY 2014.

Because GSA did not receive ample design and construction funding in FY 2012 and FY 2013 for the White Oak Campus, the design for Buildings 25, 45 (Distribution Facility) and the Communications Facility were placed on-hold in anticipation of future year funds. FDA is working with GSA on a strategy to secure GSA design and construction funds for the remaining facilities in the FY 2009 Master Plan of the 130-acre White Oak Campus. If necessary, FDA will retain existing leases and attempt to absorb program growth in existing space until the White Oak facilities are available.

FDA White Oak funding will be used for facility-related costs not funded by GSA, including relocation costs. These costs include:
information technology (IT) and telecommunications equipment for Building 75
general internal communications including audiovisual equipment
Campus infrastructure including security equipment and cabling
furniture, high density filing systems, IT and telecommunication and AV equipment
physical move for Life Sciences-Biodefense Complex, from NIH Campus and nearby leased locations, and decommissioning/surplus furniture and lab equipment in existing locations being vacated.

FIVE YEAR FUNDING TABLE – GSA RENT

The following table displays funding levels from FY 2010 through FY 2013, plus the FY 2014 request.

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2010 Actual	$177,709,000	$145,261,000	$32,448,000
FY 2011 Actual	$178,120,000	$150,763,000	$27,357,000
FY 2012 Actual	$187,655,000	$160,506,000	$27,149,000
FY 2013 CR	$210,998,000	$161,488,000	$49,510,000
FY 2014 Request	$228,034,000	$162,014,000	$66,020,000

FIVE YEAR FUNDING TABLE – OTHER RENT AND RENT-RELATED ACTIVITIES

The following table displays funding levels from FY 2010 through FY 2013, plus the FY 2014 request.

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Fiscal Year	Program Level	Budget Authority	User Fees
FY 2010 Actual	$85,668,000	$64,861,000	$20,807,000
FY 2011 Actual	$87,235,000	$61,095,000	$26,140,000
FY 2012 Actual	$89,803,000	$65,598,000	$24,205,000
FY 2013 CR	$102,239,000	$65,999,000	$36,240,000
FY 2014 Request	$120,905,000	$74,606,000	$46,299,000

FIVE YEAR FUNDING TABLE – WHITE OAK

The following table displays funding levels from FY 2010 through FY 2013, plus the FY 2014 request.

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Fiscal Year	Program Level	Budget Authority	User Fees
FY 2010 Actual	$38,536,000	$38,536,000	$0
FY 2011 Actual	$41,874,000	$38,459,000	$3,415,000
FY 2012 Actual	$43,801,000	$40,386,000	$3,415,000
FY 2013 CR	$44,302,000	$40,633,000	$3,669,000
FY 2014 Request	$61,922,000	$58,044,000	$3,878,000

Summary of Budget Request

The FY 2014 budget request for the Infrastructure Program is$410,861,000. This amount is an increase of $73,750,000 above the FY 2012 Enacted Level. This request includes $294,664,000 in Budget Authority and $116,197,000 in User Fees.

GSA Rental Payments

The FY 2014 budget request for GSA Rental Payments is $228,034,000. This amount is an increase of $22,562,000 above the FY 2012 Enacted Level. The GSA Rental increase includes $1,508,000 in Budget Authority and $21,054,000 in User Fees. The total request includes $162,014,000 in Budget Authority and $66,020,000 in User Fees.

The rental properties that provide office and laboratory space for FDA's approximately 12,000 employees are essential facilities that allow FDA to perform its vital public health mission. FY 2013 President's Budget funding request for GSA Rental Payments covers the cost of rental payments to GSA for FDA's 5.9 million square feet of GSA rented office and laboratory space, as well as payments to the Department of Homeland Security for guard services and security systems at these facilities.

Other Rent and Rent-Related

The FY 2014 budget request for Other Rent and Rent-Related is $120,905,000. This amount is an increase of $33,247,000 above the FY 2012 Enacted Level. The Other Rent and Rent-Related increase includes $9,008,000 in Budget Authority and $24,239,000 in User Fees. The total request includes $74,606,000 in Budget Authority and $46,299,000 in User Fees.

It is important that FDA keep its infrastructure up-to-date and efficient to support our staff while executing our regulatory mission. This budget request allows FDA to operate, maintain and secure its facilities in an appropriate and sustainable manner. This budget request will cover the escalating costs in commercial rent, security, service contracts, and utilities without reducing essential FDA programs.

White Oak

The FY 2014 budget request for White Oak Consolidation is $61,922,000. This amount is an increase of $17,941,000 above the FY 2012 Enacted level. The White Oak Consolidation increase includes $17,658,000 in Budget Authority and $283,000 in User Fees. The total request includes $58,044,000 in Budget Authority and $3,878,000 in User Fees.

The budget request allows FDA to fund furniture, commissioning and equipment outfitting, and decommissioning related to the Life Sciences-Biodefense Complex, including above GSA-standard costs such as specialized equipment and associated

infrastructure, e.g., reinforced floors for equipment and special ventilation systems for the BSL-3. It will also include the installation, testing, commissioning, and functioning of the specialized equipment including: building automation operation and monitoring, HEPA filter tests, air sensors, primary bio-containment device effectiveness, and room pressurization control and power tests.

The request will fund security, communications network, information technology and telecommunications equipment and infrastructure, AV equipment, and security equipment and cabling. The consolidation and operation of the safety program at White Oak to support the critical Bio-Safety Laboratories including infrastructure requirements is also included in the request.

There are currently 5,768 employees on Campus and as construction proceeds and the consolidation expands, that number will increase to 8,268 by FY 2014. The request will fund security equipment and communications networks for: the Auxiliary Support Facilities; expanded support services, such as the expansion of the Central Utility Plant, additional infrastructure to support the employees in the new laboratories and office complexes; labor and loading dock services and a centralized safety program, that was provided by NIH in the space FDA occupied on their Campus before the move. The request also provides funds for operational and logistical functions on the White Oak Campus including those vital to support the LSCB, such as specialized equipment maintenance.

Buildings and Facilities

The following table displays funding levels for FY 2012 through FY 2014.

FDA Program Resources Table
(Dollars in thousands)

	FY 2012 Enacted	FY 2012 Actual	FY 2013 CR	FY 2014 Request	FY 2014 +/FY 2012 Enacted
Program Level	$8,788	$9,080	$8,842	$8,788	$0
Budget Authority	$8,788	$9,080	$8,842	$8,788	$0
Building and Facilities	$8,788	$9,080	$8,842	$8,788	$0

Spending authority has been adjusted pursuant to PL 112-175, Section 101(c) for the applicable user fee programs.

The FDA Building and Facilities program operates under the following legal authorities:

Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 321-399)
Public Health Service Act (42 U.S.C. §238)
Energy Policy Act of 2005 (P.L. 109-058)
Chief Financial Officers Act of 1990 (P.L. 101-576)
Federal Financial Management Act of 1994 (P.L. 103-356)
Federal Property and Administrative Services Act of 1949, as amended (40 U.S.C. §§471 *et seq*.)
National Historic Preservation Act of 1966 (P.L. 89-665; 16 U.S.C. 470 *et seq.*)
Energy Independence & Security Act of 2007 (P.L. 10-140, 121 Stat. 1492)

Allocation Method: Direct Federal; Contract

Program Description Overview

The Building and Facilities Program (B&F) is a critical element of FDA's real property asset management program and provides direct support to accomplishing FDA's public health mission. B&F supports FDA's strategic goal to transform administrative systems and infrastructure to support FDA operations. Accordingly, funding is provided for new construction of mission critical laboratory, office, and support space as well as for renovations and needed repairs and improvements to 86 existing FDA-owned facilities located at six sites in the U.S. and Puerto Rico where operations critical to FDA's public health mission are being conducted. The majority of FDA's B&F funding is used for renovation as well as repair and improvement projects, which can take multiple years to complete based on project size and complexity. Project design, procurement of construction services and completion of the actual renovations, repairs and/or improvements takes in excess of 18 months on average.

* Authorities under this Act do not appear in sequence in the U.S. Code. The authorities are codified as amended in scattered sections of 21 U.S.C.

The Department of Health and Human Services (HHS) developed a Real Property Asset Management Plan (AMP), which outlines a framework and holistic approach for acquiring, managing, and disposing of real property assets. The AMP contains performance measures and benchmarks that monitor key real property asset management criteria, including mission criticality, utilization, facility condition and operating costs.

The physical condition of FDA's owned assets, which includes a substantial amount of laboratory facilities and site infrastructure, is of critical importance. A safe, suitable and reliable work environment is essential for FDA to protect the Nation's health, security, and economy. Improving and maintaining facilities often results in a positive effect on associated utilization and operating costs. An important component of FDA real property asset management is conducting facility condition assessments on a 3-year cycle. Facility condition assessments evaluate:

site infrastructure such as utility distribution systems, roads, and sidewalks
buildings to include physical systems such as architectural, civil, mechanical, and electrical as well as code compliance, life and other safety conditions, and finishes and aesthetics.
The assessments result in a list of maintenance and repair deficiencies with associated costs known as the Backlog of Maintenance and Repair (BMAR) for the site and its facilities, a plant replacement value which is the cost to replace an infrastructure item or a facility, and a Facility Condition Index (FCI) score.

The BMAR identifies and estimates costs associated with addressing needed maintenance, repairs and replacement of equipment and building systems that are approaching, at, or past their useful life. FDA's current total BMAR for its six owned sites, including renewals, is approximately $119,720,000. BMAR information is used to identify and prioritize short- and long-term projects using B&F Program funding. The FCI score is calculated using the BMAR and plant replacement value. HHS established an FCI goal of 90 percent or greater for all owned facilities. Currently, approximately 71 percent of FDA's owned assets have an FCI score below the HHS established goal and require significant repairs and improvements.

FDA utilized B&F Program funding provided in FY 2012 and plans to utilize appropriated funds in FY2013 to accomplish both mission and BMAR driven projects at each of its six owned sites. The goals of these projects are to improve the condition of these assets and the site infrastructure as well as to ensure the suitability and reliability of owned assets for conducting FDA's mission. The descriptions below are representational and not comprehensive.

FDA's Gulf Coast Seafood Laboratory site located in Dauphin Island, AL is used by the Center for Food Safety and Applied Nutrition (CFSAN) to conduct research programs related to seafood safety, especially seafood harvested from the Gulf of Mexico. During FY 2012, FDA initiated projects to ensure the continued functionality of this facility

including replacing and insulating corroded chilled water supply and return lines, repairing the sea wall, and replacing the hazardous/radioactive waste storage building. In FY 2013 FDA plans to paint the building exteriors.

The FDA Muirkirk Road Complex (MRC) located in Laurel, MD, is a campus shared by CFSAN and the Center for Veterinary Medicine (CVM) to conduct research programs related to food and animal drug safety, toxicology, microbiology, and molecular biology. In addition, laboratories at this site are used as part of the Laboratory and Food Emergency Response Networks. FDA initiated projects in mission critical laboratory buildings to replace two major air handlers, two chillers, electrical switchgear, electrical substation and water fountains contaminated with lead as well as renovating two laboratory rooms. These projects support FDA's ability to establish science-based regulatory standards and rapid responses to outbreaks.

In FY 2013 FDA plans to complete projects in mission critical laboratory space at the MRC including upgrading elevators to ensure reliability, installing a transformer and emergency electrical panels, replacing pneumatic HVAC controls with direct digital controls, renovating laboratories in support of the National Antimicrobial Resistance Monitoring System (NARMS), upgrading emergency egress lighting, and modifying a steam vent to conserve energy. FDA also plans to complete site infrastructure projects such as replacing a portion of the asphalt roadway, installing curbs and gutters, and repairing sidewalks.

The Jefferson Laboratories Complex (JLC) located in Jefferson, AR, houses the National Center for Toxicological Research (NCTR) and Office of Regulatory Affairs' (ORA) Arkansas Regional Laboratory (ARL). NCTR conducts research at this site that focuses on risk assessment, investigates toxicity, and studies the extrapolation of data from animal studies to humans, all in support of promulgating FDA regulatory policies. The ARL provides analytical laboratory support to ORA's regulatory mission in the Southwest Region. In FY 2012 FDA continued its project to significantly improve an aged electrical infrastructure at the site. In addition, projects were initiated to replace mechanical and electrical systems in a critical animal processing area, repair two roofs, renovate existing laboratories, install a new passenger elevator, continue to upgrade HVAC controls in one laboratory building, and replace a second boiler in the main boiler plant. In FY 2013 FDA plans to initiate additional site and building infrastructure projects including continued repair of the site electrical infrastructure, replacing the HVAC controls in one building, and improving an animal processing area.

The assets at FDA's San Juan District Office located in San Juan, PR, are primarily used for specialized human drug testing and analysis. FDA initiated projects to install roof access ladders needed for maintenance purposes, replace two rooftop HVAC units, replace damaged carpet with tile, replace fume hood exhaust fan motors, install water and electric meters, and modify or replace access ramps to ensure American's with Disabilities Act (ADA) compliance. In FY 2013 a project is planned that will repair or replace two building roofs. Additional projects to improve the site infrastructure are

planned, which include replacing existing domestic water tanks and installing a new electric substation for the main laboratory building.

FDA's Pacific Regional Laboratory Southwest is located in Irvine, CA. This space provides analytical laboratory support to ORA's regulatory mission in the Pacific Region. The facility also houses the Los Angeles District Office, which serves as ORA's inspection and compliance activity in the Los Angeles area. In FY 2012, FDA continued its efforts to repair excessive soil erosion beneath the parking area and recertify a high containment laboratory. Projects were also initiated to install automatic door openers in restrooms for ADA compliance and replace the front entrance security gate. If determined to be economically feasible, FDA plans to award a Utility Energy Service Contract (UESC) to complete energy conservation measures in the laboratory to improve energy efficiency and sustainability. In FY 2013, FDA plans to repair or replace the ceiling grid in a file room to eliminate a fire code violation.

The Winchester Engineering and Analytical Center (WEAC) located in Winchester, MA, is an ORA specialty laboratory used to test the safety and performance of medical devices, microwaves, and radiopharmaceuticals; to conduct radionuclide testing with food samples; and to ensure seafood freshness. FDA initiated projects in the main laboratory building to upgrade the laboratory HVAC system and associated controls, replace the transformer, replace ceiling tiles, and replace urinals and water closets with low flow fixtures. A project to replace the main security gate was also initiated. In FY 2013 FDA plans to upgrade the electrical system in the laboratory with new distribution panels and switchgear. FDA also plans to initiate a project to replace the front entrance.

Five Year Funding Table

The following table displays funding levels from FY 2010 through FY 2013.

Fiscal Year	Program Level	Budget Authority
FY 2010 Actual[1]	$22,111,000	$22,111,000
FY 2011 Actual	$12,747,000	$12,747,000
FY 2012 Actual	$9,080,000	$9,080,000
FY 2013 CR	$8,842,000	$8,842,000
FY 2014 Request	$8,788,000	$8,788,000

[1]FY 2010 includes $6,994,000 to the National Center for Natural Products Research for construction and renovation.

Summary of Budget Request

The FY 2014 budget request for the Buildings and Facilities Program is $8,788,000. This amount is equivalent to the level enacted in the FY 2012.

FDA will use the requested resources to fund various projects at its six mission critical owned sites, facilitating FDA's ability to achieve its mission, provide a safe and productive work environment, and sustain and improve the condition of its owned sites and associated buildings.

FDA prioritized a multitude of renovation, repair and improvement projects for both site infrastructure and buildings, driven by mission requirements and the Backlog of Maintenance and Repair. FDA will utilize the FY 2014 funding to complete a portion of these priority projects. Conditions and mission needs at FDA sites may change after the prioritization process that may require FDA to modify its planned projects for FY 2014, including a modification to funding allocations per site. Such flexibility is critical to ensure the highest level of support for the programs carrying out the FDA mission.

FDA plans to use FY 2014 B&F funding at its Jefferson Labs Complex (JLC) site to:

- Continue to repair the electrical distribution system on the campus, including replacement of the main electrical switchgear that serves the entire campus
- Complete the design to renovate and modernize the pre-treatment sewage plant for the site, which has reached the end of its useful life
- Complete the design to replace chillers in the plant that serves research laboratories and animal holding areas and will assist in providing increased cooling capacity in summer months
- Cepair/replace natural gas piping system
- Upgrade the control system in one laboratory building that will result in more reliable operation, a safer working environment, and energy savings
- Renovate animal rooms, procedure rooms and general animal holding areas that support critical research
- Repair cracks and other deficiencies in campus roads that if ignored could result in some roads being impassable
- Prepare a concept design for replacing the HVAC system in a laboratory building.

These projects are critical to ensure adequate, reliable site infrastructure and building operations in support of FDA's mission. This site provides analytical laboratory support to ORA's regulatory mission in the Southwest Region and houses ORA's only nanotechnology laboratory. JLC is also the home base for ORA's two mobile laboratories, and supports numerous analytical testing capabilities including dioxin testing and gulf oil spill testing.

The National Center for Toxicological Research also employs this site to support integrated research vital to regulatory decisions on products using new technologies such as nanomaterials and to increase understanding of the interaction between genetics, metabolism, nutrition, and disease susceptibility to develop dietary recommendations and individualized therapy regimens. This laboratory directly benefits public health by enabling enhanced and more efficient regulatory laboratory operations and providing the necessary environment to develop regulatory tools that facilitate premarket review, postmarket safety assurance, and rapid detection of food contamination.

Repairs and improvement projects planned for FY 2014 at the Muirkirk Road Complex (MRC) include:

- Connecting air handling units for a critical laboratory building to existing emergency power sources
  Replacing controls on 16 fume hoods and in animal rooms to improve performance and safety
- Adding sump pumps to existing manholes
- Renovating 18 walk-in boxes
- Replacing electric front doors
- Replacing windows in one of the main research laboratories
- Install restrooms in an animal research building
- Renovating an existing service building to replace windows and doors
- Correcting areas currently not ADA compliant
- Replacing poured epoxy flooring in an animal cage washing area
- Increasing emergency power capacity for a laboratory building
- Correcting plumbing deficiencies
- Installing a new pervious road to an emergency generator
- Repairing brick and mortar integrity for one building.

The MRC provides laboratory support to assure the safety of animal food, animal-derived food and the safety and efficacy of animal health products. Maintenance repairs and improvements allow the facility to accommodate state of the art instrumentation and the laboratory processes currently required to apply quick, innovative, and decisive science to animal health and food safety problems to better protect the public health. Repairs to the facility enable CFSAN and CVM scientists to meet the current and anticipated demand for applied research to support the regulatory needs of FDA.

B&F funding will be used at FDA's Irvine, CA, site in FY 2014 to upgrade the electrical distribution system by installing a power monitoring system.

The Irvine site provides analytical laboratory support to ORA's regulatory mission in the Pacific Region and houses the Los Angeles District Office, which supports ORA's inspection and compliance activity in the Los Angeles area.

Improvements planned for the main laboratory at the Winchester, MA site include:

- Designing and installing a new makeup air unit for the entire main laboratory and for one specific laboratory room
- Sealing and restriping the parking lot
- Replacing the fire annunciation panel
- Installing variable frequency drives to improve HVAC system performance and safety in certain laboratories.

WEAC provides specialized analytical services in engineering and medical devices and is the only field laboratory providing radiation analyses for both the foods and medical products programs. The site supports comprehensive evaluation of medical devices and radiation emitting appliances and recently played a critical role regarding polonium testing in beef. It is the primary field laboratory that FDA's Center for Device and Radiological Health (CDRH) relies on for analytical services and temperature-critical laboratory testing.

FDA plans to improve assets at the San Juan, PR site by:

- Repairing or replacing roofs on three buildings
- Correcting non-compliant life safety deficiencies.

This facility is the National Servicing Laboratory in PR and specializes in pharmaceutical testing and analyses. It is strategically located since Puerto Rico has a large concentration of pharmaceutical manufacturers that produce approximately 30 percent of the world's pharmaceuticals and about 60 percent of the human drugs consumed in the U.S. These improvements and repairs are essential to the infrastructure of this mission critical site and necessary to ensure continued optimal asset functionality.

FDA will replace handrails for ADA compliance and repair the seawater feed system at the Dauphin Island, AL site in FY 2014.

The Gulf Coast Seafood Laboratory located at this site is CFSAN's sole marine laboratory. Scientific staff at this location represents 80 percent of FDA research capacity for addressing seafood issues. The B&F project planned at this facility supports work on existing, emerging, and potential seafood safety issues, including continuing recovery efforts and research related to the 2010 Deepwater Horizon oil spill.

The following table provides an allocation plan by site for use of the FY 2014 funds.

FY 2014 Buildings and Facilities Allocation Plan

Site	***Total***
Jefferson Laboratories Complex (NCTR & ARL) - Jefferson, AR	$6,014,000
Muirkirk Road Complex (MOD1, MOD2, BRF) – Laurel, MD	$2,124,000
ORA Pacific Regional Laboratory SW – Irvine, CA	$35,000
Winchester Engineering and Analytical Center – Winchester, MA	$295,000
San Juan District Office – San Juan, PR	$290,000
CFSAN Gulf Coast Seafood Laboratory	$30,000
B&F PROJECT TOTAL	**$8,788,000**

FDA's B&F Program funding for FY 2014 will continue to make sustaining and improving the condition of owned real property assets a priority. Completion of these projects enhances FDA's ability to achieve its critical mission of protecting and promoting the health of the American public. In addition, several of these projects will contribute to HHS sustainability goals established in the HHS Strategic Sustainability Performance Plan developed in accordance with Executive Order 13514, "Federal Leadership in Environmental, Energy and Economic Performance." More specifically, FDA's planned FY 2014 projects will help reduce Scope 1, 2 and 3 greenhouse gas emissions by replacing aged, inefficient HVAC controls and equipment at several locations; installing a whole building make up air system in the main laboratory at WEAC; installing a power monitoring system in the Irvine, CA laboratory; and correcting plumbing deficiencies in two laboratory buildings.

Buildings and Facilities Program Activity Data[1]

Facility	Average FCI Score		
	FY 2012 Actual	FY 2013 CR	FY 2014 Request
Gulf Coast Seafood Laboratory[2]	82	82	82
Jefferson Laboratory Complex[3]	78	79	80
Muirkirk Road Complex[4]	81	81	82
Pacific Regional Laboratory Southwest[5]	97	97	97
San Juan District Office and Laboratories[6]	80	82	83
Winchester Engineering and Analytic Center[7]	48	53	53

[1]The Backlog of Maintenance and Repairs (BMAR) at each site is significant. Funding is allocated to projects at each site in an effort to reduce the BMAR and improve the average Facility Condition Index (FCI) for the site. Without ongoing repair and improvement projects, the increase in BMAR each year would result in no change or a decrease in the FCI rather than an increase. Improvements may not be realized in the fiscal year the funds are received due to timing and complexity of the project.
[2]Based on funding levels in FY 2013 and FY 2014, the BMAR for this site will decrease by approximately $30K. Remaining BMAR for this site is approximately $893K.
[3]Based on funding levels in FY 2013 and FY 2014 the BMAR for this site will decrease by approximately $5.2M. Remaining BMAR total will be approximately $73.4M.
[4]Based on funding levels in FY 2013 and FY 2014 the BMAR for this site will decrease by approximately $833K. Remaining BMAR total will be approximately $17.7M.
[5]Based on funding levels in FY 2013 and FY 2014, the BMAR for this site will decrease by approximately $28K. Remaining BMAR for this site is approximately $902K..
[6]Based on funding levels in FY 2013 and FY 2014 the BMAR for this site will decrease by approximately $305K. Remaining BMAR total will be approximately $2.4M.
[7]Based on funding levels in FY 2013 and FY 2014, the BMAR for this site will decrease by approximately $570K. Remaining BMAR total will be approximately $6.82M.

Supplementary Tables

Table of Estimates and Appropriations
Appropriations History Table – S&E and Rental Payments to GSA

Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation*
2000	1,305,869,000[1]	1,218,384,000[2]	1,180,972,000[3]	1,183,095,000[4]
2001	1,359,481,000[5]	1,240,178,000[6]	1,216,796,000[7]	1,215,446,000[8]
2002	1,377,160,000[9]	1,342,339,000[10]	1,344,386,000[11]	1,496,486,000[12]
2003	1,633,605,000[13]	1,599,602,000[14]	1,628,895,000[15]	1,621,739,000[16]
2004	1,678,632,000[17]	1,675,713,000[18]	1,670,692,000[19]	1,665,258,000[20]
2005	1,820,849,000[21]	1,788,849,000[22]	1,791,599,000[23]	1,776,784,000[24]
2006	1,849,676,000[25]	1,837,928,000[26]	1,841,959,000[27]	1,843,751,000[28]
2007	1,916,329,000[29]	1,914,382,000[30]	1,941,646,000[31]	1,790,368,000[32]
2008	2,051,801,000[33]	1,683,405,000[34]	2,276,262,000[35]	2,235,876,000[36]
2009	2,638,197,000[37]	[38]	3,168,794,000[39]	2,622,267,000[40]
2010	3,371,218,000[41]	3,230,218,000[42]	3,230,218,000	3,237,218,000[43]
2011	3,989,507,000[44]		3,720,044,000[45]	3,650,783,000[46]
2012	4,256,673,000[47]	3,599,871,000[48]	3,599,871,000[49]	3,788,336,000[50]
2013	4,142,963,000[51]			
2014	4,613,104,000[52]			

* Appropriation contains salaries and expenses (S&E), PDUFA, MDUFMA, ADUFA, AGDUFA and Tobacco.

[1] Includes $1,156,905,000 (including $99,094,000 of GSA Rent) in S&E, $149,273,000 for PDUFA ($5,860,000 is GSA rent), $15,128,000 for MQSA fee collections, $12,700,000 for Seafood Transfer User Fees, $1,500,000 for Export Certification, $4,492,000 for Certification fund, and $19,483,000 for proposed new user fees (Food Additive $8,400,000; Premarket Medical Devices $5,833,000; Foods Export Certification $5,250,000).

[2] Includes $1,090,905,000 (including $99,094,000 of GSA Rent) in S&E, $149,273,000 for PDUFA ($5,860,000 is GSA rent). This does not include $15,128,000 for MQSA fee collections.

[3] Includes $1,067,523,000 (including $99,094,000 of GSA Rent) in S&E, and $149,273,000 for PDUFA ($5,860,000 is GSA rent). Excludes $15,128,000 for MQSA fee collections, and $5,992,000 in Export Certification.

[4] Includes rescission of $2,351,000, S&E of $1,066,173,000 (including $98,876,000 of GSA Rent), and $149,273,000 for PDUFA (of which 5,860,000 is GSA rent). Excludes $14,947,000 for MQSA fee collections, $1,500,000 for Export Certification, or $22,950,000 million for drug importation that is not available until requested by the President. Also does not include $1,750,000 funded from PHSSEF for physical security counter-terrorism measures.

[5] Includes $1,156,905,000 (including $99,094,000 of GSA Rent) in S&E, $149,273,000 for PDUFA ($5,860,000 is GSA rent), $15,128,000 for MQSA fee collections, $12,700,000 for Seafood Transfer User Fees, $1,500,000 for Export Certification, $4,492,000 for Certification

fund, and $19,483,000 for proposed new user fees (Food Additive $8,400,000; Premarket Medical Devices $5,833,000; Foods Export Certification $5,250,000).

[6] Includes $1,090,905,000 (including $99,094,000 of GSA Rent) in S&E, $149,273,000 for PDUFA ($5,860,000 is GSA rent). This does not include $15,128,000 for MQSA fee collections.

[7] Includes $1,067,523,000 (including $99,094,000 of GSA Rent) in S&E, and $149,273,000 for PDUFA ($5,860,000 is GSA rent). Excludes $15,128,000 for MQSA fee collections, and $5,992,000 in Export Certification.

[8] Includes rescission of $2,351,000, S&E of $1,066,173,000 (including $98,876,000 of GSA Rent), and $149,273,000 for PDUFA (of which 5,860,000 is GSA rent). Excludes $14,947,000 for MQSA fee collections, $1,500,000 for Export Certification, or $22,950,000 million for drug importation that is not available until requested by the President. Also does not include $1,750,000 funded from PHSSEF for physical security counter-terrorism measures.

[9] Includes $1,173,673,000 (including $98,876,000 of GSA Rent) in S&E, $161,716,000 for PDUFA ($6,240,000 is GSA rent), $15,590,000 for MQSA fee collections, $1,500,000 for Export Certification, $4,681,000 for Certification fund, and $20,000,000 for proposed new user fees. Excludes $2,950,000 million for drug importation that is not available until requested by the President.

[10] Includes $1,180,623,000 (including $98,876,000 of GSA Rent) in S&E, and $161,716,000 for PDUFA ($6,240,000 is GSA rent). This does not include $15,590,000 for MQSA fee collections. This does not include the $2,950,000 the House provided for MEDSA.

[11] Includes $1,182,670,000 (including $98,876,000 of GSA Rent) in S&E, and $161,716,000 for PDUFA ($6,240,000 is GSA rent) Excludes $15,590,000 for MQSA fee collections, and $6,181,000 in Export Certification and Color Certification.

[12] Includes $1,183,670,000 (including $98,876,000 of GSA Rent) in S&E, $161,716,000 for PDUFA ($6,240,000 is GSA rent). Excludes $15,590,000 for MQSA fee collections, or $6,181,000 in Export Certification and Color Certification. Includes an additional $151,100,000 provided in the FY 2002 counter-terrorism supplemental.

[13] Includes $1,369,385,000 (including $98,556,000 of GSA Rent) in S&E, $264,220 in proposed PDUFA fees ($7,140,000 is GSA rent). Excludes $16,112,000 in MQSA fee collections, $1,500,000 in Export Certification, and $4,878,000 in Color Certification.

[14] Includes $1,376,702,000 (including $98,876,000 of GSA Rent) in S&E, and $222,900,000 for PDUFA ($7,802,000 is GSA rent). Excludes $16,112,000for MQSA fee collections, and $6,378,000 in Export Certification and Color Certification.

[15] Includes $1,383,505,000 (including $98,556,000 of GSA Rent) in S&E, and $222,900,000 for PDUFA ($7,802,000 is GSA rent) and $22,490,000 for MDUFMA. Excludes $16,112,000 for MQSA fee collections, and $6,378,000 in Export Certification and Color Certification.

[16] Includes $1,373,714,000 (including $98,233,000 of GSA Rent) in S&E, and $222,900,000 for PDUFA ($7,802,000 is GSA rent), and $25,125 in MDUFMA fees ($1,591,000 is GSA rent).

Excludes $16,112,000 in MQSA fee collections, $1,500,000 in Export Certification, and $5,237,000 in Color Certification.

[17] Includes $1,394,617,000 (including $108,876,000 of GSA Rent) in S&E, $249,825,000 in proposed PDUFA fees ($8,646,000 is GSA rent) and $29,190,000 in MDUFMA fees ($2,273,000 is GSA rent) and $5,000,000 in proposed Animal Drug User Fees ($250,000 is GSA Rent). Excludes $16,576,000 in MQSA fee collections, $1,570,000 in Export Certification, and $5,079,000 in Color Certification.

[18] Includes $1,389,234,000 (including $108,876,000 of GSA Rent) in S&E, and $249,825,000 for PDUFA ($8,646,000 is GSA rent), $31,654,000 in MDUFMA fees ($2,465,000 is GSA rent), and $5,000,000 in proposed Animal Drug User Fees (ADUFA) ($250,000 is GSA Rent). Excludes $16,575,000 in MQSA fee collections, $1,570,000 in Export Certification, and $5,079,000 in Color Certification.

[19] Includes $1,384,213,000 (including $108,233,000 of GSA Rent) in S&E, and $249,825,000 for PDUFA ($8,646,000 is GSA rent), $31,654,000 in MDUFMA fees ($2,465,000 is GSA rent), and $5,000,000 in proposed Animal Drug User Fees (ADUFA)($250,000 is GSA Rent). Excludes $16,575,000 in MQSA fee collections, $1,570,000 in Export Certification, and $5,079,000 in Color Certification.

[20] Includes $1,378,779,000 (including $107,594,000 of GSA Rent) in S&E, and $249,825,000 for PDUFA ($8,646,000 is GSA rent), $31,654,000 in MDUFMA fees ($2,465,000 is GSA rent), and $5,000,000 in proposed Animal Drug User Fees (ADUFA)($250,000 is GSA Rent). Excludes $16,575,000 in MQSA fee collections, $1,570,000 in Export Certification, and $5,079,000 in Color Certification. A$8,224,000 rescission is included.

[21] Includes $1,494,517,000 (including $107,594,000 of GSA Rent) in S&E, and $284,394,000 for PDUFA ($12,407,000 is GSA rent), $33,938,000 in MDUFMA fees ($2,643,000 is GSA rent), and $8,000,000 in proposed Animal Drug User Fees (ADUFA) ($371,000 is GSA Rent). Excludes $16,919,000 in MQSA fee collections, $1,615,000 in Export Certification, and $5,223,000 in Color Certification.

[22] Includes $1,462,517,000 (including $114,394,000 of GSA Rent) in S&E, and $284,394,000 for PDUFA ($12,407,000 is GSA rent), $33,938,000 in MDUFMA fees ($2,643,000 is GSA rent), and $8,000,000 in proposed Animal Drug User Fees (ADUFA) ($371,000 is GSA Rent). Excludes $16,919,000 in MQSA fee collections, $1,615,000 in Export Certification, and $5,223,000 in Color Certification.

[23]Includes $1,465,267,000 (including $114,394,000 of GSA Rent) in S&E, and $284,394,000 for PDUFA ($12,407,000 is GSA rent), $33,938,000 in MDUFMA fees ($2,643,000 is GSA rent), and $8,000,000 in proposed Animal Drug User Fees (ADUFA) ($371,000 is GSA Rent). Excludes $16,919,000 in MQSA fee collections, $1,615,000 in Export Certification, and $5,223,000 in Color Certification.

[24] Includes $1,450,098,000 (including $114,394,000 of GSA Rent) in S&E, and $284,394,000 for PDUFA ($12,407,000 is GSA rent), $33,938,000 in MDUFMA fees ($2,643,000 is GSA rent), and $8,354,000 in proposed Animal Drug User Fees (ADUFA) ($371,000 is GSA Rent). Excludes $16,919,000 in MQSA fee collections, $1,615,000 in Export Certification, and $5,223,000 in Color Certification.

[25]Includes $1,492,726,000 (including $117,579,000 of GSA Rent) in S&E, and $305,332,000 for PDUFA ($12,700,000 is GSA rent), $40,300,000 in MDUFMA fees ($3,203,000 is GSA rent), and $11,318,000 in proposed Animal Drug User Fees (ADUFA) ($1,371,000 is GSA Rent). Excludes $17,173,000 in MQSA fee collections, $1,639,000 in Export Certification, and $6,001,000 in Color Certification.

[26] Includes $1,480,978,000 in S&E, and $305,332,000 for PDUFA, $40,300,000 in MDUFMA fees, $11,318,000 in proposed ADUFA fees, $124,598,000 in GSA Rental Payments (Budget Authority), $12,700,000 in GSA Rent (PDUFA), $3,203,000 in GSA Rent (MDUFMA), and $1,371,000 in GSA Rent (ADUFA). Excludes $17,173,000 in MQSA fee collections, $1,639,000 in Export Certification, and $6,001,000 in Color Certification.

[27]Includes $1,486,009,000 in S&E, and $305,332,000 for PDUFA, $40,300,000 in MDUFMA fees, $11,318,000 in proposed ADUFA fees, $124,598,000 in GSA Rental Payments (Budget Authority), $12,700,000 in GSA Rent (PDUFA), $3,203,000 in GSA Rent (MDUFMA), and $1,371,000 in GSA Rent (ADUFA). Excludes $17,173,000 in MQSA fee collections, $1,639,000 in Export Certification, and $6,001,000 in Color Certification.

[28]Includes $1,486,801,000 (including $116,403,000 of GSA Rent) in S&E, and $305,332,000 for PDUFA ($12,700,000 is GSA rent), $40,300,000 in MDUFMA fees ($3,230,000 is GSA rent), and $11,318,000 in Animal Drug User Fees (ADUFA) ($1,371,000 is GSA Rent). Excludes $17,173,000 in MQSA fee collections, $1,639,000 in Export Certification, and $6,001,000 in Color Certification.

[29] Includes $1,540,399,000 (including $126,871,000 of GSA Rent) in S&E, and $320,600,000 for PDUFA ($14,501,000 is GSA rent), $43,726,000 in MDUFMA fees ($3,323,000 is GSA rent), and $11,604,000 in proposed Animal Drug User Fees (ADUFA) ($1,371,000 is GSA Rent). Excludes $17,522,000 in MQSA fee collections, $2,300,000 in Export Certification, and $6,181,000 in Color Certification.

[30] Includes $1,538,452,000 in S&E, and $320,600,000 for PDUFA fees, $43,726,000 in MDUFMA fees, $11,604,000 in ADUFA fees, $126,871,000 in GSA Rental Payments (Budget Authority), $14,501,000 in GSA Rent (PDUFA), $3,270,000 in GSA Rent (MDUFMA), and $1,371,000 in GSA Rent (ADUFA). Excludes $17,522,000 in MQSA fee collections, $2,300,000 in Export Certification, and $6,181,000 in Color Certification.

[31] Includes $1,565,716,000 in S&E, and $320,600,000 for PDUFA fees, $43,726,000 for MDUFMA fees, $11,604,000 for ADUFA fees, $126,871,000 in GSA Rental Payments (Budget Authority), $14,501,000 in GSA Rent (PDUFA), $3,270,000 in GSA Rent (MDUFMA), and $1,371,000 in GSA Rent (ADUFA). Excludes $17,522,000 in MQSA fee collections, $2,300,000 in Export Certification, and $6,181,000 in Color Certification.

[32]Reflects FY2007 Continuing Resolution. Includes $1,485,036,000 (including $116,403,000 of GSA Rent) in S&E, and $305,332,000 for PDUFA ($12,700,000 is GSA rent). Excludes $17,522,000 in MQSA fee collections, $2,300,000 in Export Certification, and $6,181,000 in Color Certification.

[33]Includes $1,635,709,000 (including $131,533,000 of GSA Rent) in S&E, and $339,195,000 for PDUFA ($21,901,000 is GSA Rent), $47,500,000 in MDUFMA fees ($3,552,000 is GSA rent), $13,696,000 in ADUFA fees ($1,441,000 is GSA), and $15,701,000 in proposed Generic Drug User Fees ($987,000 is GSA rent). Excludes $18,389,000 in MQSA fee collections, $2,500,000 in Export Certification, and $7,000,000 in Color Certification.

[34]Includes $1,669,709,000 in S&E, and $13,696,000 in ADUFA fees, $131,533,000 in GSA Rental Payments (Budget Authority), $23,498,000 in GSA Rental Payments (PDUFA), $3,622,000 in GSA Rental Payments (MDUFMA), and $1,441,000 in GSA Rental Payments (ADUFA). Excludes $18,398,000 in MQSA fee collections, $2,500,000 in Export Certification, and $7,500,000 in Color Certification.

[35]Includes $1,755,135,000 in S&E, and $459,000,000 for PDUFA fees, $48,431,000 for MDUFMA fees, $13,696,000 for ADUFA fees, $160,544,000 in GSA Rental Payments (Budget Authority), $23,498,000 in GSA Rental Payments (PDUFA), $3,622,000 in GSA Rental Payments (MDUFMA), and $1,441,000 in GSA Rental Payments (ADUFA). Excludes $18,398,000 in MQSA fee collections, $2,500,000 in Export Certification, and $7,500,000 in Color Certification.

[36] Includes $1,726,422,000 (including $130,612,000 in GSA Rent) in S&E (minus a 0.7% rescission), and $459,412,000 for PDUFA ($23,498,000 is GSA rent), $48,431,000 for MDUFMA ($3,622,000 is GSA rent), $13,696,000 for ADUFA ($1,441,000 is GSA rent). Excludes $18,398,000 in MQSA fee collections, $2,500,000 in Export Certification, and $7,500,000 in Color Certification.

[37]Includes $2,038,964,000 (including $134,351,000 of GSA Rent) in S&E, and $510,665,000 for PDUFA ($16,000,000 is GSA Rent), $52,547,000 for MDUFMA ($3,930,000 is GSA Rent), $15,260,000 for ADUFA ($839,000 is GSA Rent), $4,831,000 for AGDUFA ($305,000 is GSA Rent). Excludes $19,318,000 in MQSA fee collections, $2,600,000 in Export Certification, and $7,700,000 in Color Certification.

[38] The House did not report an FY 2009 Appropriations Bill.

[39] Includes $2,603,879,000 in S&E (including 151,381,000 in GSA Rent), and $497,108,000 for PDUFA fees (including $18,691,000 in GSA Rent), $52,547,000 for MDUFMA fees (including $839,000 in GSA Rent), $15,260,000 for ADUFA fees (including $3,930,000 in GSA Rent). Excludes MQSA fee collections, Export Certification, and Color Certification.

[40] Includes $2,038,964,000 in S&E (including $134,351,000 of GSA Rent) in S&E, and $510,665,000 for PDUFA ($16,000,000 is GSA Rent), $52,547,000 for MDUFMA ($3,930,000 is GSA Rent), $15,260,000 for ADUFA ($839,000 is GSA Rent), $4,831,000 for AGDUFA ($305,000 is GSA Rent). Excludes $19,318,000 in MQSA fee collections, $2,600,000 in Export Certification, and $7,700,000 in Color Certification.

[41] Includes $2,337,656,000 (including $146,022,000 of GSA Rent) in S&E, and $235,000,000 for Family Smoking Prevention and Tobacco Control Act (including $2,798,000 of GSA Rent), and $578,162,000 for PDUFA ($17,252,000 is GSA Rent), $57,014,000 for MDUFMA ($4,264,000 is GSA Rent), $17,280,000 for ADUFA ($885,000 is GSA Rent), $36,000,000 for GDUFA ($2,263,000 is GSA Rent), $5,106,000 for AGDUFA ($305,000 is GSA Rent). Excludes $19,318,000 in MQSA fee collections, $2,700,000 in Export Certification, and $7,700,000 in Color Certification.

[42] Includes $2,337,656,000 (including $146,022,000 of GSA Rent) in S&E, and $235,000,000 for Family Smoking Prevention and Tobacco Control Act (including $2,798,000 of GSA Rent), and $578,162,000 for PDUFA ($17,252,000 is GSA Rent), $57,014,000 for MDUFMA ($4,264,000 is GSA Rent), $17,280,000 for ADUFA ($885,000 is GSA Rent), $5,106,000 for AGDUFA ($305,000 is GSA Rent). Excludes $19,318,000 in MQSA fee collections, $2,700,000 in Export Certification, and $7,700,000 in Color Certification.

[43] Includes $2,344,656,000 (including $146,022,000 of GSA Rent) in S&E, and $235,000,000 for Family Smoking Prevention and Tobacco Control Act (including $2,798,000 of GSA Rent), and $578,162,000 for PDUFA ($17,252,000 is GSA Rent), $57,014,000 for MDUFMA ($4,264,000 is GSA Rent), $17,280,000 for ADUFA ($885,000 is GSA Rent), $5,106,000 for AGDUFA ($305,000 is GSA Rent). Excludes $19,318,000 in MQSA fee collections, $2,700,000 in Export Certification, and $7,700,000 in Color Certification.

[44] Includes $2,808,695,000 (including $172,205,000 of GSA Rent) in S&E, and $235,000,000 for Tobacco Program (including $5,491,000 of GSA Rent), and $667,057,000 for PDUFA ($19,905,000 is GSA Rent), $61,860,000 for MDUFMA ($4,626,000 is GSA Rent), $19,448,000 for ADUFA ($996,000 is GSA Rent), $38,015,000 for GDUFA ($1,841,000 is GSA Rent), $5,397,000 for AGDUFA ($322,000 is GSA Rent). Excludes $19,318,000 in MQSA fee collections, $2,700,000 in Export Certification, and $7,700,000 in Color Certification.

[45] Includes $2,516,282,000 (including $153,999,000 of GSA Rent) in S&E, and $450,000,000 for Tobacco Program (including $6,135,000 of GSA Rent), and $667,057,000 for PDUFA ($19,905,000 is GSA Rent), $61,860,000 for MDUFMA ($4,626,000 is GSA Rent), $19,448,000 for ADUFA ($996,000 is GSA Rent), $5,397,000 for AGDUFA ($322,000 is GSA Rent). Excludes $19,080,000 in MQSA fee collections, $2,700,000 in Export Certification, and $7,700,000 in Color Certification.

[46] Includes $2,447,021,000 (including $150,762,000 of GSA Rent) in S&E, and $450,000,000 for Tobacco Program (including $6,135,000 of GSA Rent), and $667,057,000 for PDUFA ($19,905,000 is GSA Rent), $61,860,000 for MDUFMA ($4,626,000 is GSA Rent), $19,448,000 for ADUFA ($996,000 is GSA Rent), $5,397,000 for AGDUFA ($322,000 is GSA Rent). Excludes $19,318,000 in MQSA fee collections, $2,700,000 in Export Certification, and $7,700,000 in Color Certification.

[47] Includes $2,730,910,000 (including $167,826,000 of GSA Rent) in S&E, and $477,000,000 for Tobacco Program (including $5,503,000 of GSA Rent), and $856,041,000 for PDUFA ($25,544,000 is GSA Rent), $67,118,000 for MDUFMA ($5,019,000 is GSA Rent), $21,768,000 for ADUFA ($1,115,000 is GSA Rent), $5,706,000 for AGDUFA ($340,000 is GSA Rent), $71,006,000 for Voluntary Qualified Importer Program ($3,920,000 is GSA Rent), $1,267,000 for Food Export Certification User Fee ($82,000 is GSA Rent), $14,700,000 for Food Re-inspection User Fee ($1,338,000 is GSA Rent), $12,346,000 for Recall User Fee ($434,000 is GSA Rent) $40,122,000 for GDUFA ($1,943,000 is GSA Rent), $14,108,000 for Medical Products Re-inspection User Fee ($1026,000 is GSA Rent), $5,338,000 for International Courier User Fee ($294,000 is GSA Rent). Excludes $19,318,000 in MQSA fee collections, $2,700,000 in Export Certification, and $7,700,000 in Color Certification.

[48] Includes $2,172,238,000 (including $156,007,000 of GSA Rent) in S&E, and $477,000,000 for Tobacco Program (including $5,503,000 of GSA Rent), and $856,041,000 for PDUFA ($25,544,000 is GSA Rent), $67,118,000 for MDUFMA ($5,019,000 is GSA Rent), $21,768,000 for ADUFA ($1,115,000 is GSA Rent), $5,706,000 for AGDUFA ($340,000 is GSA Rent), $36,006,000 for Voluntary Qualified Importer Program ($1,986,000 is GSA Rent), $14,700,000 for Food Re-inspection User Fee ($1,338,000 is GSA Rent), $12,364,000 for Recall User Fee ($434,000 is GSA Rent). Excludes $19,318,000 in MQSA fee collections, $2,700,000 in Export Certification, and $7,700,000 in Color Certification.

[49] Includes $2,172,238,000 (including $156,007,000 of GSA Rent) in S&E, and $477,000,000 for Tobacco Program (including $5,503,000 of GSA Rent), and $856,041,000 for PDUFA ($25,544,000 is GSA Rent), $67,118,000 for MDUFMA ($5,019,000 is GSA Rent), $21,768,000 for ADUFA ($1,115,000 is GSA Rent), $5,706,000 for AGDUFA ($340,000 is GSA Rent), $36,006,000 for Voluntary Qualified Importer Program ($1,986,000 is GSA Rent), $14,700,000 for Food Re-inspection User Fee ($1,338,000 is GSA Rent), $12,364,000 for Recall User Fee ($434,000 is GSA Rent). Excludes $19,318,000 in MQSA fee collections, $2,700,000 in Export Certification, and $7,700,000 in Color Certification.

[50] Includes $2,497,021,000 (including $160,506,000 of GSA Rent) in S&E, and $477,000,000 for Tobacco Program (including $5,503,000 of GSA Rent), and $702,172,000 for PDUFA ($31,928,000 is GSA Rent), $57,605,000 for MDUFMA ($4,308,000 is GSA Rent), $21,768,000 for ADUFA ($1,115,000 is GSA Rent), $5,706,000 for AGDUFA ($340,000 is GSA Rent), $14,700,000 for Food Re-inspection User Fee ($1,338,000 is GSA Rent), $12,364,000 for Recall User Fee ($434,000 is GSA Rent). Excludes $19,318,000 in MQSA fee collections, $3,337,000 in Export Certification, $4,582 Priority Review Vouchers, and $7,843,000 in Color Certification.

[51] Includes $2,512,303,000 (including $161,488,000 of GSA Rent) in S&E, and $479,919,000 for Tobacco Program (including $5,537,000 of GSA Rent), and $718,669,000 for PDUFA ($21,569,000 is GSA Rent), $57,958,000 for MDUFMA ($4,334,000 is GSA Rent), $21,901,000 for ADUFA ($1,122,000 is GSA Rent), $5,741,000 for AGDUFA ($342,000 is GSA Rent), $14,790,000 for Food Re-inspection User Fee ($1,346,000 is GSA Rent), $12,440,000 for Recall User Fee ($437,000 is GSA Rent) $299,000,000 for GDUFA ($13,815,000 is GSA Rent), $20,242,000 for Biosimilars User Fee ($1,008,000 is GSA Rent). Excludes $19,318,000 in MQSA fee collections, $4,604,000 in Export Certification, and $7,843,000 in Color Certification.

[52] Includes $2,548,905,000 (including $162,014,000 of GSA Rent) in S&E, and $534,000,000 for Tobacco Program (including $9,974,000 of GSA Rent), and $760,000,000 for PDUFA ($22,997,000 is GSA Rent), $114,833,000 for MDUFMA ($6,216,000 is GSA Rent), $23,600,000 for ADUFA ($1,180,000 is GSA Rent), $7,328,000 for AGDUFA ($440,000 is GSA Rent), $15,367,000 for Food Re-inspection User Fee ($1,399,000 is GSA Rent), $12,925,000 for Recall User Fee ($454,000 is GSA Rent) $305,996,000 for GDUFA ($14,318,000 is GSA Rent), $20,716,000 for Biosimilars User Fee ($1,033,000 is GSA Rent), $15,043000 for Medical Products Re-inspection User Fee ($1,094,000 is GSA Rent), $5,692,000 for International Courier User Fee ($313,000 is GSA Rent), $58,936,000 for Food Establishment Registration and Inspection User Fee ($1,438,000 is GSA Rent), $165,690,000 for Food Import User Fee ($4,330,000 is GSA Rent) $19,074,000 for Cosmetics User Fee ($900 is GSA Rent), $4,999,000 for Food Contact Notification User Fee ($114,000 is GSA Rent). Excludes $19,318,000 in MQSA fee collections, $4,604,000 in Export Certification, and $7,843,000 in Color Certification.

Food and Drug Administration
Table of Estimates and Appropriations
Appropriations History Table – Buildings and Facilities

Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
2000	31,750,000[1]	31,750,000	8,350,000	11,350,000
2001	31,350,000[2]	11,350,000	31,350,000	31,350,000
2002	34,281,000[3]	34,281,000	34,281,000	34,281,000
2003	8,000,000[4]	8,000,000	11,000,000[5]	7,948,000[6]
2004	11,500,000[7]	6,000,000	7,948,000	6,959,000[8]
2005	6,959,000[9]	-6,959,000	-6,959,000	-6,959,000
2006	7,000,000	5,000,000	7,000,000	7,920,000
2007	4,950,000	4,950,000	4,950,000	4,950,000[10]
2008	4,950,000	4,950,000	4,950,000	2,433,000
2009	2,433,000	12,433,000	12,433,000	12,433,000
2010	12,433,000	12,433,000	12,433,000	12,433,000
2011	12,433,000	9,980,000	9,980,000	9,980,000
2012	13,055,000	8,788,000	8,788,000	8,788,000
2013	8,842,000			
2014	8,788,000			

[1] Includes $20,400,000 for construction of Phase I of the new Los Angeles Laboratory and $3,000,000 for continuing modernization of the ARL.
[2] Includes $20,000,000 for construction of Phase I of the new Los Angeles Laboratory and $3,000,000 for continuing modernization of the ARL.
[3] Includes $23,000,000 for construction of Phase II of the new Los Angeles Laboratory and $3,000,000 for continuing modernization of the ARL.
[4] Reflects a reduction of $26,281,000 to centralize of B&F construction activities at the Department.
[5] Includes $3,000,000 to complete ARL.
[6] Includes $8,000,000 in Appropriated funds with a rescission of $52,000.
[7] Includes $3,500,000 to complete ARL.
[8] Includes Final Conference amount of $7,000,000 with a $41,000 rescission.
[9] Includes a $6,959,000 decrease to fund high priority programs.
[10] Reflects FY 2007 current rate.

Food and Drug Administration
Object Class Tables
Budget Authority
(dollars in thousands)

	FY 2012 Actual	FY 2014 Budget
Personnel compensation:		
Full-time permanent (11.1)	$756,540	$786,828
Other than full-time permanent (11.3)	$101,572	$105,639
Other personnel compensation (11.5)	$53,991	$56,153
Military personnel (11.7)	$60,479	$61,605
Special personnel services payments (11.8)	$670	$696
Subtotal personnel compensation	**$973,252**	**$1,010,920**
Civilian benefits (12.1)	$266,926	$277,612
Military benefits (12.2)	$31,533	$32,120
Benefits to former personnel (13.0)	$322	$335
Total Pay Costs	**$1,272,033**	**$1,320,988**
Travel and transportation of persons (21.0)	$47,235	$48,811
Transportation of things (22.0)	$4,530	$4,681
Rental payments to GSA (23.1)	$160,506	$162,014
Rent payments to others (23.2)	$3,269	$3,313
Communication, utilities, and misc. charges (23.3)	$37,024	$38,259
Printing and reproduction (24.0)	$2,635	$2,723
Other Contractual Services:		
Consulting services (25.1)	$46,657	$48,213
Other services (25.2)	$358,736	$340,137
Purchase of goods and svcs from Govt Acts. (25.3)	$224,701	$232,194
Operation and maintenance of facilities (25.4)	$56,726	$58,618
Research and Development Contracts (25.5)	$32,704	$33,795
Operation and maintenance of equipment (25.7)	$48,390	$50,004
Subtotal Other Contractual Services	**$767,915**	**$762,961**
Supplies and materials (26.0)	$42,204	$43,611
Equipment (31.0)	$54,375	$56,188
Land and Structures (32.0)	$4,357	$4,502
Grants, subsidies, and contributions (41.0)	$109,672	$108,818
Insurance claims and indemnities (42.0)	$778	$804
Interest and dividends (43.0)	$22	$22
Total Non-Pay Costs	**$1,234,520**	**$1,236,705**
Total Budget Authority by Object Class	**$2,506,553**	**$2,557,693**

Food and Drug Administration
User Fees
(dollars in thousands)

	FY 2012 Actual	FY 2014 Budget
Personnel compensation:		
Full-time permanent (11.1)	$335,749	$739,363
Other than full-time permanent (11.3)	$41,709	$97,670
Other personnel compensation (11.5)	$21,746	$53,719
Military personnel (11.7)	$25,091	$33,208
Special personnel services payments (11.8)	$366	$977
Subtotal personnel compensation	**$424,660**	**$924,936**
Civilian benefits (12.1)	$114,890	$251,012
Military benefits (12.2)	$13,042	$16,604
Benefits to former personnel (13.0)	$78	$1,953
Total Pay Costs	**$552,670**	**$1,194,505**
Travel and transportation of persons (21.0)	$9,224	$19,497
Transportation of things (22.0)	$375	$975
Rental payments to GSA (23.1)	$27,149	$66,020
Rent payments to others (23.2)	$98	$78
Communication, utilities, and misc. charges (23.3)	$10,831	$19,511
Printing and reproduction (24.0)	$4,488	$1,950
Other Contractual Services:		
Consulting services (25.1)	$70,513	$92,610
Other services (25.2)	$118,273	$217,298
Purchase of goods and svcs from Govt Acts. (25.3)	$161,623	$283,679
Operation and maintenance of facilities (25.4)	$15,513	$50,692
Research and Development Contracts (25.5)	$16,576	$44,843
Operation and maintenance of equipment (25.7)	$12,244	$8,774
Subtotal Other Contractual Services	**$394,743**	**$697,894**
Supplies and materials (26.0)	$11,605	$20,472
Equipment (31.0)	$10,025	$24,371
Land and Structures (32.0)	$341	$0
Grants, subsidies, and contributions (41.0)	$27,866	$50,692
Insurance claims and indemnities (42.0)	$190	$0
Interest and dividends (43.0)	$5	$0
Total Non-Pay Costs	**$496,938**	**$901,459**
Total User Fee by Object Class	**$1,049,608**	**$2,095,964**

Food and Drug Administration
Program Level

(dollars in thousands)

	FY 2012 Actual	FY 2014 Budget
Personnel compensation:		
Full-time permanent (11.1)	$1,092,288	$1,526,191
Other than full-time permanent (11.3)	$143,281	$203,309
Other personnel compensation (11.5)	$75,737	$109,871
Military personnel (11.7)	$85,571	$94,812
Special personnel services payments (11.8)	$1,036	$1,673
Subtotal personnel compensation	**$1,397,912**	**$1,935,856**
Civilian benefits (12.1)	$381,816	$528,625
Military benefits (12.2)	$44,575	$48,724
Benefits to former personnel (13.0)	$400	$2,288
Total Pay Costs	**$1,824,703**	**$2,515,493**
Travel and transportation of persons (21.0)	$56,459	$68,307
Transportation of things (22.0)	$4,905	$5,656
Rental payments to GSA (23.1)	$187,655	$228,034
Rent payments to others (23.2)	$3,366	$3,391
Communication, utilities, and misc. charges (23.3)	$47,856	$57,770
Printing and reproduction (24.0)	$7,122	$4,672
Other Contractual Services:		
Consulting services (25.1)	$117,170	$140,823
Other services (25.2)	$477,009	$557,435
Purchase of goods and svcs from Govt Acts. (25.3)	$386,324	$515,872
Operation and maintenance of facilities (25.4)	$72,239	$109,309
Research and Development Contracts (25.5)	$49,281	$78,638
Operation and maintenance of equipment (25.7)	$60,634	$58,777
Subtotal Other Contractual Services	**$1,162,658**	**$1,460,855**
Supplies and materials (26.0)	$53,808	$64,083
Equipment (31.0)	$64,399	$80,559
Land and Structures (32.0)	$4,698	$4,502
Grants, subsidies, and contributions (41.0)	$137,537	$159,510
Insurance claims and indemnities (42.0)	$968	$804
Interest and dividends (43.0)	$27	$22
Total Non-Pay Costs	**$1,731,458**	**$2,138,164**
Total Program Level by Object Class	**$3,556,161**	**$4,653,657**

Food and Drug Administration
Salaries and Expenses

(dollars in thousands)

	FY 2012 Actual	FY 2014 Budget	FY 2014 +/- FY 2012
Personnel compensation:			
Full-time permanent (11.1)	$756,540	$786,828	$30,289
Other than full-time permanent (11.3)	$101,572	$105,639	$4,067
Other personnel compensation (11.5)	$53,991	$56,153	$2,162
Military personnel (11.7)	$60,479	$61,605	$1,125
Special personnel services payments (11.8)	$670	$696	$27
Subtotal personnel compensation	**$973,252**	**$1,010,920**	**$37,669**
Civilian benefits (12.1)	$266,926	$277,612	$10,687
Military benefits (12.2)	$31,533	$32,120	$587
Benefits to former personnel (13.0)	$322	$335	$13
Total Pay Costs	**$1,272,033**	**$1,320,988**	**$48,955**
Travel and transportation of persons (21.0)	$47,235	$48,811	$1,576
Transportation of things (22.0)	$4,530	$4,681	$151
Rent payments to others (23.2)	$3,269	$3,313	$104
Communication, utilities, and misc. charges (23.3)	$37,024	$38,259	$1,235
Printing and reproduction (24.0)	$2,635	$2,723	$88
Other Contractual Services:			
Consulting services (25.1)	$46,657	$48,213	$1,556
Other services (25.2)	$358,736	$340,137	-$18,665
Purchase of goods and svcs from Govt Acts. (25.3)	$224,701	$232,194	$7,495
Operation and maintenance of facilities (25.4)	$56,726	$58,618	$1,892
Research and Development Contracts (25.5)	$32,704	$33,795	$1,091
Operation and maintenance of equipment (25.7)	$48,390	$50,004	$1,614
Subtotal Other Contractual Services	**$767,915**	**$762,961**	**-$5,017**
Supplies and materials (26.0)	$42,204	$43,611	$1,408
Total Non-Pay Costs	**$904,812**	**$904,358**	**-$455**
Rental payments to GSA (23.1)	$160,506	$162,014	$1,508
Grand Total, Salaries and Expenses and Rent	**$2,337,350**	**$2,387,359**	**$50,008**

Food and Drug Administration
Detail of Full-Time Equivalent (FTE) Employment
Program Level

Project[1]	FY 2012 Actual			FY 2013			FY 2014 Estimate		
	Civilian	Military	Total FY 2012 Actual	Civilian	Military	Total FY 2013	Civilian	Military	Total FY 2014 Estimate
Center for Food Safety and Applied Nutrition	844	38	882	875	38	913	956	38	994
Center for Drug Evaluation and Research	2,885	387	3,272	3,257	387	3,644	3,530	387	3,917
Center for Biologics Evaluation and Research	1,027	62	1,089	1,046	62	1,108	1,053	62	1,115
Center for Veterinary Medicine	509	6	515	513	6	519	518	6	524
Center for Devices and Radiological Health	1,404	106	1,510	1,424	106	1,530	1,397	106	1,503
National Center for Toxological Research	250	19	269	254	19	273	253	19	272
Office of Regulatory Affairs	4,162	289	4,451	4,480	289	4,769	4,966	289	5,255
Headquarters and Office of the Commissioner	940	54	994	1,069	54	1,123	1,162	54	1,216
Export Certification	18		18	18		18	22	-	22
Color Certification	36		36	37		37	37	-	37
Family Smoking Prevention and Tabacco Control Act	346		346	482		482	570		570
TOTAL	12,421	961	13,382	13,455	961	14,416	14,463	961	15,424

[1] FY 2012, FY 2013 and FY 2014 do not include an estimated 101 reimbursable, 1 CRADA, 42 PEPFAR, 12 IDDA FTE and the associated funds.

Five Year History of GS/GM Average Grade

Year	Grade
FY 2008	13
FY 2009	13
FY 2010	13
FY 2011	13
FY 2012	13

Food and Drug Administration
Distribution of FTE by Grade

	FY 2012 Actuals	FY 2013 CR	FY 2014 Request
Executive Level I			
Executive Level II			
Executive Level III			
Executive Level IV	1	1	1
Executive Level V			
Total, Exec. Level	1	1	1
ES	56	56	56
Total ES	56	56	56
GS-15	943	1,029	1,112
GS-14	2,515	2,743	2,966
GS-13	3,532	3,852	4,165
GS-12	2,037	2,222	2,402
GS-11	914	997	1,078
GS-10	23	25	27
GS-9	577	629	680
GS-8	128	140	151
GS-7	365	398	430
GS-6	60	65	71
GS-5	75	82	88
GS-4	130	142	153
GS-3	68	74	80
GS-2	27	30	32
GS-1	3	3	4
Subtotal, GS	11,397	12,431	13,439
AL			
ST/SL	2	2	2
RS	39	39	39
CC - 08/07/06	240	240	240
CC - Other	721	721	721
Subtotal, CC	961	961	961
AD (includes Title 42)	883	883	883
Wage Grade	26	26	26
Consultants	17	17	17
Total FTE (End of Year) [1]	13,382	14,416	15,424
Average ES Level	3	3	3
Average ES Salary	$169,378	$169,378	$169,378
Average GS grade	12	12	12
Average GS salary	$96,310	$96,791	$97,273

[1] FY 2012, FY 2013 and FY 2014 do not include an estimated 101 reimbursable, 1 CRADA, 42 PEPFAR, 12 IDDA FTE and the associated funds.

Food and Drug Administration
Programs Proposed for Elimination

No Programs Proposed for Elimination.

Food and Drug Administration
HHS Enterprise IT and Government-Wide E-Gov Initiatives

FDA E-Government Allocation Statement:

The **FDA** will use **$1,241,162** of its **FY 2014** budget to support the following government-wide E-Government initiatives:

E-Government Initiatives and Lines of Business	FY 2014	FDA
Budget Formulation and Execution LoB	$105,000	$13,263
Disaster Assist Improvement Plan	$121,154	$0
E-Rulemaking (moved from FFS)	$975,000	$419,477
Federal Health Architecture LoB	$3,522,000	$535,100
Financial Management LoB /1	$230,616	$26,610
Geospatial LoB	$50,000	$0
GovBenefits.gov	$390,982	$0
Grants.gov	$7,844,642	$79,753
Human Resources Management LoB	$130,435	$23,054
IAE - Loans and Grants	$5,006,640	$54,154
Integrated Acquisition Environment	$2,359,151	$89,751
Total	$20,735,620	$1,241,162

* Specific levels presented here are subject to change, as redistributions to meet changes in resource demands are assessed.

Prospective benefits from the continued operation and development and enhancement of these initiatives and lines of business include:

Benefits.Gov: GovBenefits.gov is the official benefits website of the Federal Government, providing all citizens with information and eligibility prescreening services for more than 1,000 federally funded benefit and assistance programs. Helping to eliminate redundant solutions and promote efficiency in government, Benefits.gov also creates and hosts multiple other websites on behalf of its 17 Federal partner agencies – including GovLoans.gov, DisasterAssistance.gov and BEST.SSA.gov – each of which leverages Benefits.gov's existing architecture, infrastructure and management team. More than 90 HHS programs use Benefit.gov as a portal for providing services to citizens.

Budget Formulation and Execution: The focus of the Budget Formulation and Execution Line of Business (BFE LoB) is to build a "budget office of the future" by promoting information sharing across government agency budget offices and building a "community of practice." Through this government-wide effort, the budget community is developing common tools and identifying best practices for all aspects of budget formulation and execution.

Goals of the BFE LoB include improvement and enhancements of:

- Efficiency and effectiveness of agency and central processes for formulating and executing the Federal Budget;
- Integration and standardized exchange of budget formulation, execution, planning, performance measurement, and financial management information and activities across the government;
- Capabilities for analyzing budget formulation, execution, planning, performance, and financial information in support of decision-making;
- Capabilities for aligning programs and their outputs and outcomes with budget levels and actual costs to institutionalize budget and performance integration; and
- Efficiency and effectiveness of the Federal budgeting workforce.

Disaster Assistance Improvement Plan (DAIP): "The objective of the Disaster Assistance Improvement Program (DAIP) is to simplify the process of identifying and applying for disaster assistance as required by Executive Order 13411. To that end, the program created DisasterAssistance.gov, a user-friendly Web portal that consolidates disaster assistance information and application interfaces to multiple Federal forms of assistance (FOAs) in one place. Individuals in need of assistance following a presidentially declared disaster designated for individual assistance can now go to DisasterAssistance.gov to register online.

Currently, 17 Federal agencies, including HHS, contribute to the portal, which offers applications for or information about almost 70 FOAs as well as news, information and resources to help individuals, families and businesses prepare for, respond to and recover from disasters.".

E-Rulemaking: E-Rulemaking provides citizens one access point to view and comment on rules and notices. This program and its supporting application allow agencies to fulfill the E-Government Act of 2002 requirement to ensure a publicly accessible website containing electronic dockets for regulations.

The E-Rulemaking program includes two important components:

- Regulations.gov: the public website that provides citizens, small businesses, educators, multinational corporations, civic organizations, and all levels of government one-stop Internet access to view, download, and submit comments on all Federal regulations. Agencies are required to ensure their public regulatory dockets are electronically accessible and searchable using Regulations.gov and accept electronic submissions via the website.

- Federal Docket Management System (FDMS): an advanced “back-end” docket management system that provides Department and Agency staff with improved internal docket management functionality and the ability to publicly post all relevant documents on Regulations.gov (e.g., Federal Register documents, proposed rules, notices, supporting analyses, and public comments).

Federal Health Architecture: Creates a consistent Federal framework that improves coordination and collaboration on national Health Information Technology (HIT) Solutions; improves efficiency, standardization, reliability and availability to improve the exchange of comprehensive health information solutions, including health care delivery; and, to provide appropriate patient access to improved health data. HHS works closely with federal partners, state, local and tribal governments, including clients, consultants, collaborators and stakeholders who benefit directly from common vocabularies and technology standards through increased information sharing, increased efficiency, decreased technical support burdens and decreased costs.

Financial and Grants Management: Financial Management supports efficient and improved business performance while ensuring integrity in accountability, financial controls and mission effectiveness by enhancing process improvements; achieving cost savings; standardizing business processes and data models; promoting seamless data exchanges between Federal agencies; and, strengthening internal controls.

Grants Management supports end-to-end grants management activities promoting improved customer service; decision making; financial management processes; efficiency of reporting procedure; and, post-award closeout actions. The Administration for Children and Families (ACF) is a GMLOB consortia lead, which has allowed ACF to take on customers external to HHS. These additional agency users have allowed HHS to reduce overhead costs for internal HHS users.

Additionally, NIH is an internally HHS-designated Center of Excellence. This effort has allowed HHS agencies using the NIH system to reduce grants management costs. Both efforts have allowed HHS to achieve economies of scale and efficiencies, as well as streamlining and standardization of grants processes, thus reducing overall HHS costs for grants management systems and processes.

Geospatial: Promotes coordination and alignment of geospatial data collection and maintenance among all levels of government: provides one-stop web access to geospatial information through development of a portal; encourages collaborative planning for future investments in geospatial data; expands partnerships that help leverage investments and reduce duplication; and, facilitates partnerships and collaborative approaches in the sharing and stewardship of data. Up-to-date accessible information helps leverage resources and support programs: economic development, environmental quality and homeland security. HHS registers its geospatial data, making it available from the single access point.

Grants.Gov: Grants.gov is the Federal Government's single website providing information on over 1000 grant programs – representing approximately $500 billion awarded by the 26 grant-making agencies and other Federal grant-making organizations. The initiative enables Federal agencies to publish grant funding opportunities and application packages online while allowing over 1 million organizations that comprise the grant community (state, local, and tribal governments, education and research organizations, non-profit organizations, public housing agencies, and individuals) to search for opportunities and download, complete, and electronically submit applications.

All 26 major Federal grant making agencies posted 100% of their synopses for discretionary funding opportunity announcements on Grants.gov.

Human Resources Management: The HR LoB vision is to create government-wide, modern, cost-effective, standardized, and interoperable HR solutions to provide common core functionality to support the strategic management of Human Resources through the establishment of Shared Service Centers (SSCs). Driven from a business perspective rather than a technology focus, the solutions will address distinct business improvements enhancing the government's performance of HR and payroll services in support of agency missions delivering services to citizens. The HR LoB concept of operations calls for agencies to receive core services from an HR LoB provider. These core HR services are defined as personnel action processing, compensation management (payroll) and benefits management. Leveraging shared services solutions will allow the HR LoB to significantly improve HR and payroll service delivery, save taxpayer dollars, and reduce administrative burdens. HHS will begin using the National Business Center, which operates the HR LoB solution, in FY 2014 to support its core HR services.

Integrated Acquisitions Environment: Since 2002, the Integrated Acquisition Environment (IAE) has offered a portfolio of nine acquisition services which facilitates all phases of the Federal acquisition lifecycle for buyers, sellers, and the public – bringing transparency and visibility to the process of Federal acquisition. These services evolved from the "Adopt, Adapt, Acquire" strategy.

Integrated Acquisitions Environment – Loans & Grants: All agencies participating in the posting and/or making Federal awards are required by the Federal Funding Accountability and Transparency Act (Transparency Act) of 2006 and the American Recovery and Reinvestment Act of 2009 (ARRA) to disclose award and sub-award information on a publicly accessible website. FFATA requires OMB to lead the development of a single, searchable website through which the public can readily access Federal award information.

FDA Specific Exhibits

Functional Activity Tables

FY 2014 President's Budget	PREMARKET														POSTMARKET																	
	REVIEW		APPLIED RESEARCH		OUTREACH COORDINATION				INSPECTIONS				TOTAL		OUTREACH COORDINATION		APPLIED RESEARCH		LABORATORY ANALYSIS				INSPECTIONS						TOTAL		FDA	
					DOMESTIC		FOREIGN		DOMESTIC		FOREIGN				COMPLIANCE				DOMESTIC		IMPORTS		DOMESTIC		FOREIGN		IMPORTS					
	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE
FOODS																																
Center for Food Safety & Applied Nutrition	16,212	70	12,139	54	5,069	34	684	4	139	-	40	-	34,283	162	100,881	328	156,867	368	-	-	-	-	20,341	90	7,952	46	-	-	286,041	832	320,324	994
Field Activities													-	-	182,784	639	3,162	14	77,907	345	95,137	416	142,886	734	34,873	132	249,531	836	786,280	3,116	786,280	3,116
Reinspection User Fee (non-add): Field													-	-									*7,134*	*48*					*7,134*	*48*	*7,134*	*48*
Food Feed Recall User Fee (non-add): Center													-	-	*485*	*2*													*485*	*2*	*485*	*2*
Food Feed Recall User Fee (non-add): Field													-	-									*9,823*	*23*					*9,823*	*23*	*9,823*	*23*
Proposed Food Establishment Registration and Inspection User Fee (non-add): Center															*8,802*	*11*	*8,788*	*7*					*3,812*	*6*	*1,418*	*4*			*22,820*	*28*	*22,820*	*28*
Proposed Food Establishment Registration and Inspection User Fee (non-add): Field													-	-	*18,560*	*19*							*8,277*	*1*					*26,837*	*20*	*26,837*	*20*
Proposed Food Imports User Fee (non-add): Center															*8,583*	*8*	*5,227*	*2*											*13,810*	*10*	*13,810*	*10*
Proposed Food Imports User Fee (non-add): Field													-	-	*8,843*	*37*					*1,578*	*2*							*120,935*	*227*	*120,935*	*227*
Proposed Cosmetics User Fee (non-add) : Center													-	-	*12,253*	*42*													*12,253*	*42*	*12,253*	*42*
Proposed Cosmetics User Fee (non-add): Field													-	-					*490*	*2*	*1,469*	*6*	*1,714*	*7*			*734*	*3*	*4,407*	*18*	*4,407*	*18*
Proposed International Courier User Fee (non-add): Field													-	-													*735*	*3*	*735*	*3*	*735*	*3*
Proposed Food Contact Notification User Fee (non-add): Center	*4,548*	*7*											*4,548*	*7*									-	-			-	-	-	-	-	-
Proposed Food Contact Notification User Fee (non-add): Field													-																			
FOODS TOTAL	**16,212**	**70**	**12,139**	**54**	**5,069**	**34**	**684**	**4**	**139**	**-**	**40**	**-**	**34,283**	**162**	**283,665**	**967**	**160,029**	**382**	**77,907**	**345**	**95,137**	**416**	**163,227**	**824**	**42,825**	**178**	**249,531**	**836**	**1,072,321**	**3,948**	**1,106,604**	**4,110**
HUMAN DRUGS																																
Center for Drug Evaluation & Research	688,423	2,498	51,688	101	30,028	122	11,223	52	10,858	52	10,638	53	802,858	2,878	252,206	824	17,510	84	3,140	18	498	3	11,627	62	7,439	38	1,813	10	*294,233*	*1,039*	1,097,091	3,917
Field Activities									26,614	140	36,022	158	62,636	298	31,079	169			14,842	76	3,788	22	24,941	164	49,208	197	8,590	39	*132,448*	*667*	195,084	965
PDUFA (non-add): Center	*341,490*	*1,417*	*22,475*	*60*	*21,096*	*85*	*8,500*	*39*	*7,572*	*34*	*6,518*	*30*	*407,651*	*1,665*	*126,874*	*450*													*126,874*	*450*	*534,525*	*2,115*
PDUFA (non-add): Field									*7,230*	*30*	*3,678*	*17*	*10,908*	*47*															-	-	*10,908*	*47*
GDUFA (non-add): Center	*170,828*	*359*											*170,828*	*359*	*36,647*	*85*													*36,647*	*85*	*207,475*	*444*
GDUFA (non-add): Field											*16,692*	*54*	*16,692*	*54*											*36,331*	*119*			*36,331*	*119*	*53,023*	*173*
Proposed Medical Product Reinspection user fee (non-add): Field													-										*2,804*	*18*					*2,804*	*18*	*2,804*	*18*
BSUFA (non-add): Center	*15,304*	*59*											*15,304*	*59*	*372*	-													*372*	-	*15,676*	*59*
BSUFA (non-add): Field									*793*	*3*	*529*	*2*	*1,322*	*5*															-	-	*1,322*	*5*
Proposed International Courier User Fee (non-add): Center																																
Proposed International Courier User Fee (non-add): Field													-														*491*	*2*	*491*	*2*	*491*	*2*
HUMAN DRUGS TOTAL	**688,423**	**2,498**	**51,688**	**101**	**30,028**	**122**	**11,223**	**52**	**37,472**	**192**	**46,660**	**211**	**865,494**	**3,176**	**283,285**	**993**	**17,510**	**84**	**17,982**	**94**	**4,286**	**25**	**36,568**	**226**	**56,647**	**235**	**10,403**	**49**	**426,681**	**1,706**	**1,292,175**	**4,882**
BIOLOGICS																																
Center for Biologics Evaluation & Research	204,036	725	24,323	153	27,282	98	730	2	2,046	7			258,417	985	30,834	117	246	2					2,920	11					*34,000*	*130*	292,417	1,115
Field Activities									5,120	21	203	1	5,323	22	7,421	43							28,961	160	2,421	9	1,403	7	*40,206*	*219*	45,529	241
PDUFA (non-add): Center	*93,958*	*349*			*12,804*	*48*			*931*	*3*			*107,693*	*400*	*2,300*	*8*													*2,300*	*8*	*109,993*	*408*
PDUFA (non-add): Field									*4,581*	*6*			*4,581*	*6*															-	-	*4,581*	*6*
MDUFMA (non-add): Center	*8,781*	*34*			*980*	*4*	*35*	-	*155*	*1*			*9,951*	*39*	*350*	*1*													*350*	*1*	*10,301*	*40*
MDUFMA (non-add): Field									*192*	*1*			*192*	*1*															-	-	*192*	*1*
Proposed Medical Products Reinspection user fee (non-add): Field																							*572*	*3*					*572*	*3*	*572*	*3*
BSUFA (non-add): Center	*774*	*3*											*774*	*3*																	*774*	*3*
GDUFA (non-add): Center	*774*	*3*											*774*	*3*															-	-	*774*	*3*
BIOLOGICS TOTAL	**204,036**	**725**	**24,323**	**153**	**27,282**	**98**	**730**	**2**	**7,166**	**28**	**203**	**1**	**263,740**	**1,007**	**38,255**	**160**	**246**	**2**	**-**	**-**	**-**	**-**	**31,881**	**171**	**2,421**	**9**	**1,403**	**7**	**74,206**	**349**	**337,946**	**1,356**
ANIMAL DRUGS & FEEDS																																
Center for Veterinary Medicine	63,062	267	3,562	18	917	5							67,541	290	38,635	181	12,250	53											50,885	234	118,426	524
Field Activities									2,041	8	829	4	2,870	12	18,577	79	357	2	5,878	33	1,247	7	22,346	141	1,873	18	19,180	48	69,457	328	72,327	340
Proposed ADUFA (non-add): Center	*20,768*	*67*											*20,768*	*67*															-	-	*20,768*	*67*
Proposed ADUFA (non-add): Field									*472*	*1*			*472*	*1*															-	-	*472*	*1*
Proposed AGDUFA (non-add): Center	*6,302*	*20*											*6,302*	*20*															-	-	*6,302*	*20*
Proposed AGDUFA (non-add): Field									*220*	*1*			*220*	*1*															-	-	*220*	*1*
Food Reinspection User Fee (non-add): Field													-	-									*2,666*	*18*					*2,666*	*18*	*2,666*	*18*
Proposed Medical Products Reinspection user fee (non-add): Field													-	-									*143*	*1*					*143*	*1*	*143*	*1*
Proposed Food Establishment Registration & Inspection User Fee (non-add): Center													-	-	*1,526*	*6*	-	-	-	-	-	-	-	-	-	-	-	-	*1,526*	*6*	*1,526*	*6*
Proposed Food Establishment Registration & Inspection User Fee (non-add): Field													-	-	*1,018*	*2*	-	-											*1,018*	*2*	*1,018*	*2*
Proposed Food Import User Fee (non-add): Center																																
Proposed Food Import User Fee (non-add): Field													-	-	*956*	*4*									*564*	*1*	*11,900*	*21*	*13,420*	*26*	*13,420*	*26*
Food and Feed Recall User Fee (non-add): Center															*1,439*	*6*													*1,439*	*6*	*1,439*	*6*
Food and Feed Recall User Fee (non-add): Field													-										*668*	*2*					*668*	*2*	*668*	*2*
ANIMAL DRUGS & FEEDS TOTAL	**63,062**	**267**	**3,562**	**18**	**917**	**5**	**-**	**-**	**2,041**	**8**	**829**	**4**	**70,411**	**302**	**57,212**	**260**	**12,607**	**55**	**5,878**	**33**	**1,247**	**7**	**22,346**	**141**	**1,873**	**18**	**19,180**	**48**	**120,342**	**562**	**190,753**	**864**
DEVICES AND RADIOLOGICAL HEALTH																																
Center for Devices & Radiological Health	182,727	832	17,967	72	15,321	72	3,594	17					219,608	994	94,100	434	2,377	11	16,161	63									112,639	509	332,247	1,503
Field Activities									8,789	45	543	2	*9,332*	*47*	22,696	123	222	1	4,204	19	3,319	15	43,436	209	8,815	38	10,775	71	*93,467*	*476*	102,799	523
MOSA (non-add): Center															6,003	31													6,003	31	*6,003*	*31*
MOSA (non-add): Field													-	-	*7,223*	*5*							*5,854*	*3*					*13,077*	*8*	*13,077*	*8*
MDUFMA (non-add): Center	*61,819*	*267*	*4,466*	*14*	*4,799*	*23*	*1,126*	*5*					72,210	*309*	*12,462*	*41*	*75*	-	*1,433*	*6*									13,970	*47*	*86,180*	*356*
MDUFMA (non-add): Field									*1,822*	*10*			*1,822*	*10*									91	-					*91*	-	*1,913*	*10*
Proposed Medical Products Reinspection User Fee (non-add): Field													-	-									*3,651*	*24*					*3,651*	*24*	*3,651*	*24*
Proposed International Courier User Fee (non-add): Field													-	-													*3,678*	*15*	*3,678*	*15*	*3,678*	*15*
DEVICES TOTAL	**182,727**	**832**	**17,967**	**72**	**15,321**	**72**	**3,594**	**17**	**8,789**	**45**	**543**	**2**	**228,941**	**1,041**	**116,796**	**557**	**2,599**	**12**	**20,365**	**82**	**3,319**	**15**	**43,436**	**209**	**8,815**	**38**	**10,775**	**71**	**206,105**	**985**	**435,046**	**2,026**
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH			**34,507**	**148**									**34,507**	**148**	-	-	**24,987**	**124**	-	-	-	-	-	-	-	-	-	-	24,987	124	**59,494**	**272**
CENTER FOR TOBACCO PRODUCTS																																
Center for Tobacco Products			12,371	14									12,371	14	219,585	257	123,275	144	2,659	3			128,597	152					474,116	556	486,487	570
Field													-	-	5,150	24			3,228	15			4,304	20			2,307	11	14,989	70	14,989	70
TOBACCO TOTAL	**-**	**-**	**12,371**	**14**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**12,371**	**14**	**224,735**	**281**	**123,275**	**144**	**5,887**	**18**	**-**	**-**	**132,901**	**172**	**-**	**-**	**2,307**	**11**	**489,105**	**626**	**501,476**	**640**
HEADQUARTERS / OFFICE OF THE COMMISSIONER	**75,110**	**359**	**21,304**	**46**	**5,024**	**27**	**1,037**	**16**	**3,554**	**22**	**3,085**	**18**	**109,115**	**488**	**83,130**	**313**	**21,809**	**66**	**8,181**	**47**	**6,646**	**38**	**28,950**	**142**	**17,195**	**39**	**23,041**	**83**	**188,952**	**728**	**298,067**	**1,216**
SUB-TOTAL:	**1,229,570**	**4,751**	**177,861**	**606**	**83,641**	**359**	**17,269**	**91**	**59,161**	**295**	**51,360**	**236**	**1,618,862**	**6,337**	**1,087,078**	**3,531**	**363,061**	**869**	**136,201**	**619**	**110,634**	**501**	**459,309**	**1,885**	**129,775**	**517**	**316,640**	**1,105**	**2,602,699**	**9,028**	**4,221,561**	**15,365**
Other Rent and Rent-Related (incl. White Oak Relocation)																															**182,827**	
GSA Rent																															**228,034**	
Export Certification User Fee																															**4,604**	**22**
Colors Certification User Fee																															**7,843**	**37**
Priority Review Voucher User Fee																															-	
Buildings and Facilities																															**8,788**	
TOTAL S&E PROGRAM:																															**4,653,657**	**15,424**

Food and Drug Administration
HIV/AIDS Resource Funding
(Dollars in Thousands)

Program	FY 2010 Actual	FY 2011 Actual	FY 2012 Actual	FY 2013 Estimate	FY 2014 Estimate
Human Drugs	*$33,443*	*$36,572*	*$32,243*	*$32,243*	*$32,243*
Biologics	*$33,387*	*$33,189*	*$34,122*	*$34,122*	*$34,122*
Medical Devices	*$1,846*	*$1,697*	*$1,721*	*$1,721*	*$1,721*
Toxicological	*$235*	*$132*	*$0*	*$0*	*$0*
Other Activities	*$3,529*	*$3,469*	*$3,469*	*$3,469*	*$3,469*
Field Activity	*$36,256*	*$38,586*	*$37,720*	*$37,720*	*$37,720*
Total HIV/AIDS	**$ 108,696**	**$ 113,645**	**$ 109,275**	**$ 109,275**	**$ 109,275**

Food and Drug Administration
User Fee History

User Fee History
(Dollars in Thousands)

USER FEES: Enacted Appropriations	FY 2011 Enacted		FY 2012 Enacted		FY 2013 Estimate[1]		FY 2014 Estimate	
	FTE	$	FTE	$	FTE	$	FTE	$
Definite Appropriations:								
PDUFA								
- Human Drugs	*1,849*	*$469,559*	*1,980*	*$490,877*	*2,070*	*$505,745*	*2,115*	*$534,526*
- Biologics	*341*	*$96,624*	*355*	*$101,010*	*400*	*$104,071*	*408*	*$109,993*
- Office of Regulatory Affairs	*54*	*$13,608*	*56*	*$14,225*	*53*	*$14,656*	*53*	*$15,489*
- Headquarters and Office of the Commissioner	*172*	*$40,693*	*195*	*$42,541*	*195*	*$43,829*	*202*	*$46,323*
- GSA Rent		*$19,905*		*$31,928*		*$21,569*		*$22,997*
- Other Rent and Rent Related Activities		*$23,253*		*$17,996*		*$25,130*		*$26,794*
- FDA Consolidation at White Oak		*$3,415*		*$3,595*		*$3,669*		*$3,878*
Subtotal, PDUFA	**2,416**	**$667,057**	**2,586**	**$702,172**	**2,718**	**$718,669**	**2,778**	**$760,000**
MDUFA								
- Medical Devices and Radiological Health	*32*	*$12,009*	*209*	*$33,177*	*325*	*$33,380*	*356*	*$86,180*
- Biologics	*230*	*$35,627*	*28*	*$11,183*	*37*	*$11,251*	*40*	*$10,301*
- Office of Regulatory Affairs	*13*	*$1,688*	*13*	*$1,572*	*13*	*$1,582*	*11*	*$2,105*
- Headquarters and Office of the Commissioner	*23*	*$6,417*	*21*	*$5,975*	*28*	*$6,012*	*29*	*$6,485*
- GSA Rent		*$4,626*		*$4,308*		*$4,334*		*$6,216*
- Other Rent and Rent Related Activities		*$1,493*		*$1,390*		*$1,399*		*$3,546*
Subtotal, MDUFA	**298**	**$61,860**	**271**	**$57,605**	**403**	**$57,958**	**436**	**$114,833**
ADUFA [2]								
- Animal Drugs and Feeds	*66*	*$17,209*	*66*	*$19,261*	*67*	*$19,379*	*67*	*$20,768*
- Office of Regulatory Affairs	*1*	*$281*	*2*	*$315*	*1*	*$317*	*1*	*$472*
- Headquarters and Office of the Commissioner	*4*	*$780*	*4*	*$873*	*4*	*$878*	*4*	*$944*
- GSA Rent		*$996*		*$1,115*		*$1,122*		*$1,180*
- Other Rent and Rent Related Activities		*$182*		*$204*		*$205*		*$236*
Subtotal, ADUFA	**71**	**$19,448**	**72**	**$21,768**	**72**	**$21,901**	**72**	**$23,600**
AGDUFA [2]								
- Animal Drugs and Feeds	*20*	*$4,632*	*20*	*$4,898*	*20*	*$4,928*	*20*	*$6,302*
- Office of Regulatory Affairs	*1*	*$151*	*1*	*$160*	*1*	*$161*	*1*	*$220*
- Headquarters and Office of the Commissioner	*1*	*$216*	*1*	*$228*	*1*	*$230*	*1*	*$293*
- GSA Rent		*$322*		*$340*		*$342*		*$440*
- Other Rent and Rent Related Activities		*$76*		*$80*		*$80*		*$73*
Subtotal, AGDUFA	**22**	**$5,397**	**22**	**$5,706**	**22**	**$5,741**	**22**	**$7,328**
TOBACCO								
- Tobacco Products	*345*	*$415,567*	366	$448,501	482	$451,246	570	$486,487
- Office of Regulatory Affairs	*25*	*$5,896*	26	$6,250	41	$6,288	70	$14,989
- Headquarters and Office of the Commissioner	*32*	*$14,336*	34	$15,196	34	$15,289	52	$19,500
- GSA Rent		*$6,135*		$5,503		$5,537		$3,050
- Other Rent and Rent Related Activities		*$8,066*		$1,550		$1,559		$9,974
Subtotal, Tobacco	**402**	**$450,000**	**426**	**$477,000**	**557**	**$479,919**	**692**	**$534,000**
Voluntary Qualified Importer Program: Subtotal, VQIP					-	-	-	-
Proposed Definite Appropriations:								
Medical Products Reinspection User Fee:								
- Office of Regulatory Affairs							***46***	***7,170***
-Human Drug Program							*18*	*2,804*
- Biologics Program							*3*	*572*
-Animal Drugs Program							*1*	*$143*
-Devices and Radiological Health Program							*24*	*$3,651*
- Headquarters and Office of the Commissioner							*10*	*$6,293*
- GSA Rent								*$1,094*
- Other Rent and Rent Related Activities								*$486*
Subtotal, Medical Products Reinspection							***56***	***15,043***
International Courier User Fee:								
- Office of Regulatory Affairs							***20***	***4,904***
-Foods Program							*3*	*735*
- Human Drugs Program							***2***	***491***
-Devices and Radiological Health Program							*15*	*$3,678*
- Headquarters and Office of the Commissioner							*1*	*$295*
- GSA Rent								*$313*
- Other Rent and Rent Related Activities								*$180*
Subtotal, Medical Products Reinspection							***21***	***5,692***
Food Facility Registration and Inspection User Fee								
- Foods							*28*	*22,820*
- Animal Drugs and Fees							*6*	*1,526*
- Office of Regulatory Affairs							*22*	*27,855*
- Headquarters and Office of the Commissioner							*13*	*4,486*
- GSA Rent								*1,438*
- Other Rent and Rent Related Activities								*811*
Subtotal, Food Facility Regist and Insp							**69**	**58,936**

Food Import User Fee								
- Foods							*10*	*$13,810*
- Animal Drugs and Fees							*6*	*$1,439*
- Office of Regulatory Affairs							*253*	*$134,355*
- Headquarters and Office of the Commissioner							*32*	*$9,278*
- GSA Rent								*$4,330*
- Other Rent and Rent Related Activities								*$2,478*
Subtotal, Food Import							**301**	**$165,690**
Cosmetics User Fee								
- Foods							*42*	*$12,253*
- Office of Regulatory Affairs							*18*	*$4,407*
- Headquarters and Office of the Commissioner							*3*	*$1,000*
- GSA Rent								*$900*
- Other Rent and Rent Related Activities								*$514*
Subtotal, Cosmetics							**63**	**$19,074**
Food Contact Substance Notification User Fee								
- Foods							*7*	*$4,548*
- Office of Regulatory Affairs							*0*	*$0*
- Headquarters and Office of the Commissioner							*1*	*$272*
- GSA Rent								*$114*
- Other Rent and Rent Related Activities								*$65*
Subtotal, Food Contact							**8**	**$4,999**
Indefininate Appropriations:								
Generic Prescription Drug User Fee (GDUFA):								
- Human Drugs					*250*	*$202,731*	*444*	*$207,475*
- Biologics							*3*	*$774*
- Office of Regulatory Affairs					*150*	*$51,811*	*173*	*$53,023*
- Headquarters and Office of the Commissioner					*50*	*$24,196*	*70*	*$23,988*
- GSA Rent						*$13,815*		*$14,138*
- Other Rent and Rent Related Activities						*$6,447*		*$6,598*
Subtotal, GDUFA					***450***	***$299,000***	***690***	***$305,996***
Biosimilar User Fee (BsUFA)								
- Human Drugs					*59*	*$15,304*	*59*	*$15,676*
- Biologics					*3*	*$774*	*3*	*$774*
- Office of Regulatory Affairs					*5*	*$1,290*	*5*	*$1,322*
- Headquarters and Office of the Commissioner					*5*	*$1,290*	*5*	*$1,321*
- GSA Rent						*$1,008*		*$1,033*
- Other Rent and Rent Related Activities						*$576*		*$590*
Subtotal, BsUFA					**72**	**$20,242**	**72**	**$20,716**
Food Reinspection								
- Office of Regulatory Affairs			***66***	***9,375***	***66***	***9,433***	***66***	***9,800***
Foods Program Estimate			*48*	*$6,825*	*48*	*$6,867*	*48*	*$7,134*
Human Drugs Program Estimate			*18*	*$2,550*	*18*	*$2,566*	*18*	*$2,666*
- Headquarters and Office of the Commissioner			*7*	*$3,395*	*7*	*$3,416*	*7*	*$3,549*
- GSA Rent				*$1,338*		*$1,346*		*$1,399*
- Other Rent and Rent Related Activities				*$592*		*$595*		*$619*
Subtotal, Food Reinspection			***73***	***14,700***	***73***	***14,790***	***73***	***15,367***
Food and Feed Recall								
- Foods			*2*	*$464*	*2*	*$467*	*2*	*$485*
- Animal Drugs and Feeds			*2*	*$521*	*2*	*$524*	*2*	*$545*
- Office of Regulatory Affairs			*25*	*$10,036*	*25*	*$10,098*	*25*	*$10,491*
- Headquarters and Office of the Commissioner			*2*	*$661*	*2*	*$665*	*2*	*$691*
- GSA Rent				*$434*		*$437*		*$454*
- Other Rent and Rent Related Activities				*$248*		*$249*		*$259*
Subtotal, Food and Feed Recall			**31**	**$12,364**	**31**	**$12,440**	**31**	**$12,925**
MQSA								
- Devices and Radiological Health	*23*	*$6,003*	*26*	*$6,003*	*31*	*$6,003*	*31*	*$6,003*
- Office of Regulatory Affairs	*8*	*$13,077*	*8*	*$13,077*	*8*	*$13,077*	*8*	*$13,077*
- Headquarters and Office of the Commissioner	*2*	*$238*	*2*	*$238*	*2*	*$238*	*2*	*$238*
Subtotal, MQSA	**33**	**$19,318**	**36**	**$19,318**	**41**	**$19,318**	**41**	**$19,318**
Export Certification	**20**	**$2,700**	**15**	**$3,337**	**18**	**$4,604**	**22**	**$4,604**
Color Certification Fund	**38**	**$7,700**	**37**	**$7,843**	**37**	**$7,843**	**37**	**$7,843**
Priority Review Vouchers		**$0**		**$4,582**		**$0**		**$0**
Total, User Fees	**3,300**	**1,233,480**	**3,569**	**1,326,395**	**4,494**	**1,662,425**	**5,484**	**2,095,964**

[1] Spending authority has been adjusted pursuant to PL 112-175, Section 101(c) for the applicable user fee programs.

[2] ADUFA and AGDUFA authorizations expire October 1, 2013. FY 2014 estimates for ADUFA and AGDUFA are based on the legislative proposals to reauthorize these user fees that were transmitted to Congress in February 2013.

USER FEES: Obligations

	FY 2009 Actual		FY 2010 Actual		FY 2011 Actual		FY 2012 Actual	
	FTE	$	FTE	$	FTE	$	FTE	$
PDUFA:								
- Human Drugs	*1,636*	*$351,021*	*1,849*	*$409,029*	*1,980*	*$456,222*	*2,058*	*$461,288*
- Biologics	*326*	*$79,122*	*341*	*$80,664*	*355*	*$87,443*	*400*	*$92,570*
- Office of Regulatory Affairs	*55*	*$9,905*	*54*	*$9,988*	*56*	*$9,943*	*54*	*$10,170*
- Headquarters and Office of the Commissioner	*166*	*$35,018*	*172*	*$28,954*	*195*	*$28,982*	*194*	*$29,682*
- GSA Rent		*$16,886*		*$25,632*		*$18,568*		*$18,742*
- Other Rent and Rent Related Activities		*$20,099*		*$18,991*		*$23,253*		*$21,062*
- White Oak		*$0*		*$0*		*$3,415*		*$3,415*
Subtotal, PDUFA	**2,183**	**$512,051**	**2,416**	**$573,258**	**2,587**	**$627,826**	**2,706**	**$636,929**
MDUFA								
- Medical Devices and Radiological Health	*176*	*$32,462*	*232*	*$41,256*	*248*	*$39,987*	*325*	*$52,537*
- Biologics	*29*	*$7,227*	*30*	*$6,990*	*36*	*$8,531*	*36*	*$8,118*
- Office of Regulatory Affairs	*9*	*$1,352*	*13*	*$1,901*	*13*	*$2,015*	*13*	*$2,065*
- Headquarters and Office of the Commissioner	*22*	*$3,389*	*23*	*$3,592*	*26*	*$3,983*	*28*	*$3,791*
- GSA Rent		*$1,982*		*$2,361*		*$3,200*		*$2,347*
- Other Rent and Rent Related Activities		*$892*		*$1,087*		*$1,541*		*$1,470*
Subtotal, MDUFMA	**236**	**$47,304**	**298**	**$57,187**	**323**	**$59,257**	**403**	**$70,328**
ADUFA								
- Animal Drugs and Feeds	*64*	*$11,792*	*65*	*$14,926*	*67*	*$14,967*	*61*	*$14,690*
- Office of Regulatory Affairs	*2*	*$250*	*2*	*$264*	*2*	*$302*	*1*	*$175*
- Headquarters and Office of the Commissioner	*4*	*$594*	*4*	*$631*	*4*	*$651*	*5*	*$637*
- GSA Rent		*$628*		*$659*		*$672*		*$559*
- Other Rent and Rent Related Activities		*$115*		*$121*		*$41*		*$76*
Subtotal, ADUFA	**70**	**$13,379**	**71**	**$16,601**	**73**	**$16,633**	**67**	**$16,137**
AGDUFA								
- Animal Drugs and Feeds	*11*	*$1,854*	*22*	*$4,225*	*23*	*$4,321*	*20*	*$4,070*
- Office of Regulatory Affairs	*2*	*$54*	*1*	*$144*	*1*	*$156*		*$11*
- Headquarters and Office of the Commissioner	*1*	*$17*	*1*	*$158*	*1*	*$165*	*1*	*$168*
- GSA Rent		*$100*		*$105*		*$18*		*$99*
- Other Rent and Rent Related Activities		*$100*		*$105*		*$26*		*$18*
Subtotal, AGDUFA	**14**	**$2,125**	**24**	**$4,737**	**25**	**$4,686**	**21**	**$4,366**
TOBACCO								
- Tobacco Products			*84*	*$62,355*	*225*	*$135,027*	*346*	*$271,695*
- Office of Regulatory Affairs			*6*	*$2,063*	*10*	*$1,198*	*33*	*$5,441*
- Headquarters and Office of the Commissioner			*23*	*$3,375*	*21*	*$2,810*	*47*	*$11,594*
- GSA Rent				*$3,691*		*$4,899*		*$5,402*
- Other Rent and Rent Related Activities				*$503*		*$1,279*		*$1,579*
Subtotal, Tobacco			**113**	**$71,987**	**256**	**$145,213**	**426**	**$295,711**
Food Reinspection								**$0**
Food and Feed Recall								**$0**
MQSA	31	$13,731	33	$14,064	41	$14,639	41	$14,527
Export Certification	10	$1,651	20	$3,663	15	$3,337	18	$4,214
Color Certification Fund	38	$7,407	38	$6,768	37	$7,843	36	$7,396
Subtotal	**79**	**$22,789**	**91**	**$24,495**	**93**	**$25,819**	**95**	**$26,137**
Total, FDA	**2,582**	**$597,648**	**3,013**	**$748,265**	**3,357**	**$879,434**	**3,718**	**$1,049,608**

USER FEES: Collections

	FY 2011 Actual	FY 2012 Actual	FY 2013 Estimate[1]	FY 2014 Estimate
	$000	$000	$000	$000
PDUFA Collections	$594,608	$671,946	$718,669	$760,000
MDUFA Collections	$71,447	$68,350	$57,958	$114,833
ADUFA Collections	$17,680	$21,031	$21,901	$23,600
AGDUFA Collections	$4,970	$7,492	$5,741	$7,328
Tobacco Collections[3]	$448,151	$411,160	$479,919	$534,000
MQSA Collections	$15,512	$15,261	$19,318	$19,318
Export Certification	$3,404	$3,448	$4,604	$4,604
Color Certification Fund	$8,062	$8,282	$7,843	$7,843
Food Reinspection	$0	$0	$14,790	$15,367
Food and Feed Recall	$0	$0	$12,440	$12,925
GDUFA Collections			$299,000	$305,996
BsUFA Collections			$20,242	$20,716
Priority Review Voucher	$0	$4,582	$0	$0
Medical Products Reinspection				$15,043
International Courier				$5,692
Food Facility Registration and Inspection				$58,936
Food Import				$165,690
Cosmetics				$19,074
Food Contact				$4,999
Total, User Fees Collections	**$1,163,834**	**$1,211,552**	**$1,662,425**	**$2,095,964**

[3] The Family Smoking Prevention and Tobacco Control Act authorizes quarterly collection of industry user fees. As required by law, FDA bills and collects Tobacco user fees at the end of each quarter, which means that the fourth quarter collections are not available for obligation until the first quarter of the following fiscal year.

Summary of Central Account

FDA uses the Central Account to pay for centralized services and assessment costs. Generally the most efficient way to purchase services that have FDA-wide benefit is centrally from one account. The savings that result allow FDA components to have more resources available for public health programs.

When a charge universally benefits all FDA components—centers, headquarters offices, and the Office of Regulatory Affairs (ORA)—the charges are based on the components' full-time equivalent (FTE) staff. Charges may also be limited to the specific FDA components that benefit from the services.

There are four main categories of expenditures from the Central Account: Program Support Center (PSC), Facilities, Information Technology, and Support Services.

Program Support Center (PSC)

- PSC assessments cover centralized services that PSC provides to FDA for administrative and program support. These services include financial management services, building operations, Federal Occupational Health services, payroll systems, and enterprise applications.

Facilities

- The Facilities category includes the NIH Management Fund that supports lab and office space occupied by CBER and CDER at the NIH campus and the rent-related costs such as utilities, maintenance, janitorial and guard services incurred by NCTR in support of the Arkansas Regional lab. This category also includes recurring costs for maintenance of alarm systems, lock work for FDA headquarters, x-ray machines, and explosive detection devices for FDA sites across the nation. Lastly, Facilities includes non-recurring services such as one-time security system installations to meet minimum security standards as required by the Department of Homeland Security and Presidential directives.

Information Technology (IT)

- IT expenditures include five subcategories: IT security, telecommunications costs, operations and maintenance of agency-wide systems, enterprise agreements (including enterprise information management), and miscellaneous IT costs, such as a Departmental tap for the consolidated grants management system and NIH computer charges.

Support Services

- Support Services expenditures cover: taps and assessments for HHS Department-wide initiatives, Secretary Priorities, joint funding arrangements with other HHS agencies, mail and courier services for mail rooms, General Service Administration Fleet Mail vehicles, Pitney Bowes equipment and maintenance, records storage at the National Archives and Records Administration, interpreting services, ethics review, A-123 activities, A-76 studies, succession planning, Equal Employment Opportunity settlements, and other employee services such as transit subsidy.

The following tables reflect program level expenditures by budget authority and user fees from the FDA Central Account for FY 2012 actual and estimated FY 2013 and FY 2014.

Central Budget Tables

	PSC		Facilities		Information Technology		Support Services		Total	
	BA	UF	BA	UF	BA	UF	BA	UF	BA	UF
FOODS										
Center for Food Safety & Applied Nutrition	1,867	838	1,529	686	3,945	1,770	3,580	1,606	10,921	4,900
Field Activities	6,350	2,911	4,672	2,142	12,061	5,529	10,945	5,018	34,028	15,600
FOODS TOTAL	8,217	3,749	6,201	2,828	16,006	7,299	14,525	6,624	44,949	20,500
HUMAN DRUGS										
Center for Drug Evaluation & Research	3,677	16,887	3,895	7,575	10,054	17,633	9,124	17,742	26,750	59,837
Field Activities	1,735	655	1,276	293	3,294	359	2,989	686	9,294	1,992
HUMAN DRUGS TOTAL	5,412	17,542	5,171	7,867	13,348	17,992	12,113	18,428	36,044	61,829
BIOLOGICS										
Center for Biologics Evaluation & Research	2,222	2,990	1,712	1,340	4,419	3,984	4,010	3,158	12,363	11,472
Field Activities	556	166	408	75	1,054	102	957	174	2,975	517
BIOLOGICS TOTAL	2,779	3,156	2,120	1,415	5,473	4,087	4,967	3,332	15,339	11,989
ANIMAL DRUGS & FEEDS										
Center for Veterinary Medicine	425	275	535	123	1,380	318	1,252	289	3,592	1,005
Field Activities	687		506		1,307		1,186		3,686	-
ANIMAL DRUGS & FEEDS TOTAL	1,113	275	1,041	123	2,687	318	2,438	289	7,279	1,005
DEVICES AND RADIOLOGICAL HEALTH										
Center for Devices & Radiological Health	1,378	567	1,576	254	4,067	1,254	3,690	595	10,711	2,670
Field Activities	1,118	39	822	18	2,123	86	1,926	41	5,989	183
DEVICES TOTAL	2,496	605	2,398	272	6,190	1,340	5,616	636	16,700	2,852
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH	446	-	357	-	922	-	837	-	2,562	-
HEADQUARTERS/OFFICE OF THE COMMISSIONER	6,067	-	3,285	-	8,478	-	7,694	-	25,524	-
TOTAL BA and UF:	26,530	25,326	20,573	12,505	53,104	31,035	48,190	29,309	148,397	98,175

DHHS Charges and Assessments Narrative

ASSESSMENTS: $1,731,048

Interagency Council Funds $88,808
Funding to support government-wide financial, information technology, procurement, human capital, and other management activities.

NIH eRA Grants Management System $153,693
Pilot phase to support migration of FDA Grants Data into the Department's consolidated eRA Grants Management System

Office of Commissioned Corps Force Management $96,856
SGLI reimbursement

Department Ethics Program $1,374,944
The Office of General Counsel provides legal and related support services to the FDA.

Federal Audit Clearinghouse $597

Leading EDGE Program $16,150

FEE FOR SERVICE: $27,870,758

Program Support Center/FOH/OS $11,900,677:

Provides various services to the FDA, including some Information and Systems Management Services. The following is a breakdown of costs.

Financial Management Services (FMS): $598,475

Strategic Acquisition Service: $422,777

Administrative Operations Service: $10,879,425
Includes costs for security, building operations, shredding, storage, graphics, property disposal, transhare, mail and payroll services.

Federal Occupational Health (FOH): $1,715,000
FDA agency health units and services

Information & System Management Services $14,255,081:

Freedom of Information (FOIA) $238,650

Unified Financial Management Systems (UFMS) $5,832,000
The Program Support Center delivers and manages O&M Services for UFMS by supporting daily operations.

HCAS O&M $1,969,082
HCAS O&M services provide support for daily operations of the HCAS application.

Telecommunication Services $541,349
Telecommunications team offers expertise on technical design & support for customer systems.

HHS NET $1,038,000

Enterprise Application $4,636,000
Services include activities for HHS civilian employees and Commissioned Corps Officers, and maintenance and operation of the systems housing current and historical pay and leave records.

JOINTLY FUNDED PROJECTS: $30,456,627

Human Resource Center – Rockville $23,003,000

Enterprise Information Management $3,413,466
FDA's contribution to the HHS Enterprise Infrastructure Fund. Funds are used for Enterprise Information Technology programs/projects outlined in the Enterprise Information Technology Strategic Plan or benefitting the corporate enterprise, such as enterprise buys/licenses.

International Health Bilateral Agreement $1,093,646
Agreement to provide funding in support of the bilateral-multilateral activities performed on behalf of the Public Service by the Office of Global Health Affairs

Other Jointly Funded Projects $2,946,515:

CFO Audit of Financial Statements $1,397,000
Audit services to be performed at the Food and Drug Administration (FDA) in support of the fiscal year 2010 financial statement audit of the Department of Health and Human Services (DHHS) and its components, and related services contracted and monitored by Office of the Inspector General (OIG)

Office of Public Health/Blood Safety $300,000
Agreement to provide funding for the advisory committee on Blood Safety

Regional Health Administrators $308,010
IAG with OS/Office of Public Health & Science to support ten Regional Health Administrators. Their core mission is to promote understanding of and improvements in public health and to conduct specific management and control functions within their respective regions.

President's Council on Bioethics $294,000
TAP to fund the council which advises the President of Bioethical issues related to the advances in biomedical science and technology

Media Monitoring $127,635
Provides Agency leadership and staff with the latest analysis of what the media is reporting about Department-wide and Agency-specific priorities, initiatives, and programs

Intra-department Council on Native American Affairs $15,909
IAG with DHHS, Administration on Children and Families, for staff and administrative support for the Interdepartmental Council for Native American Affairs (ICNAA), to conduct semi-annual Council meetings, Executive Committee meetings and assignments.

National Science Advisory Board for Biosecurity $325,000
Agreement with NIH to develop improved biosecurity measures for classes of legitimate biological research that could be misused to threaten public health or national security

NIH Negotiation of Indirect Cost Rates (New) $11,000
Agreement with NIH/OD to support costs associated with the negotiation of indirect cost rates with commercial organizations

HHS Broadcast Studio (New) $100,000
The HHS broadcost studio is a resource for all of HHS. It is a communication tool used for departmental messaging, both to internal and external audiences and is key to the government-wide open government initiative.

OPM USAJOBS $67,961
Fees charged by OPM to Federal Agencies to cover the cost of providing Federal Employment Information and services. OPM assesses an annual per-capita-fee on all paid employees with access to USAJOBs. The cost is distributed within HHS based on each OPDIV percentage of the Departments total FTE.

DHHS Charges and Assessment Table
FY 2012 Actual, and FY 2013 / 2014 Estimates

Activity	FY 2012 Actual	FY 2013 Estimate	FY 2014 Estimate
ASSESSMENTS	**1,731,048**	**964,790**	**965,100**
FEE FOR SERVICE	**27,870,758**	**34,124,411**	**35,453,960**
Program Support Center/FOH/OS	*11,900,677*	*17,546,112*	*18,796,960*
Federal Occupational Health	*1,715,000*	*2,887,005*	*2,938,000*
Information System Management Service	*14,255,081*	*13,691,294*	*13,719,000*
JOINTLY FUNDED PROJECTS	**30,456,627**	**9,461,735**	**9,090,152**
Human Resources Consolidation Costs	*23,003,000*	*2,532,258*	*2,532,000*
Unified Financial Management System Upgrade	*-*	*1,011,000*	*1,011,000*
Enterprise Information Management	*3,413,466*	*2,894,889*	*2,500,896*
International Health - Bilateral Agreement	*1,093,646*	*1,148,338*	*1,148,338*
Other Jointly Funded Projects	*2,946,515*	*1,875,250*	*1,897,918*
TOTAL	**60,058,433**	**44,550,936**	**45,509,212**

Geographic Distribution of Facilities

*Building ID (FDA-1)	Building Name	FDA Center	City	State	FDA Region Code	Ownership (HHS-15)
AMDL	Ammendale Building - Glassware Washing and Document Rooms	CDER/CFSAN	BELTSVILLE	MD	HEADQUARTERS	GSA Leased
BRF	Beltsville Research Facility - Laboratory	CFSAN	LAUREL	MD	HEADQUARTERS	FDA Owned
BRF-1	Beltsville Research Facility - Support Bldg	CFSAN	LAUREL	MD	HEADQUARTERS	FDA Owned
BRF-2	Beltsville Research Facility - Carpentry Shop	CFSAN	LAUREL	MD	HEADQUARTERS	FDA Owned
BRF-3	Beltsville Research Facility - Maintenance Building	CFSAN	LAUREL	MD	HEADQUARTERS	FDA Owned
BRF-4	Beltsville Research Facility - Hazmat Trailers	CFSAN	LAUREL	MD	HEADQUARTERS	FDA Owned
BRF-5	Beltsville Research Facility - Block Building	CFSAN	LAUREL	MD	HEADQUARTERS	FDA Owned
BS-BLU	Border Station - Port Huron, MI	ORA	PORT HURON	MI	CENTRAL-CHICAGO	GSA Leased
BS-BOS	Resident Post - Boston, MA	ORA	BOSTON	MA	NORTHEAST-NEWYORK	GSA Leased
BS-CAL1	Border Station - Calais, ME	ORA	CALAIS	ME	NORTHEAST-NEWYORK	GSA Owned
BS-CALEX	Border Station - Calexico, CA - Annex Building	ORA	CALEXICO	CA	PACIFIC-OAKLAND	GSA Leased
BS-HIGH	Border Station - Highgate Springs, VT	ORA	HIGHGATE SPRINGS	VT	NORTHEAST-NEWYORK	GSA Owned
BS-HLT2	Border Station - Houlton, ME - Truck Facility	ORA	HOULTON	ME	NORTHEAST-NEWYORK	GSA Owned
BS-HLT3	Border Station - Houlton, ME - LPOE	ORA	HOULTON	ME	NORTHEAST-NEWYORK	GSA Owned
BS-LAR3	Border Station - Laredo TX - Village Plaza	ORA	LAREDO	TX	SOUTHWEST-DALLAS	GSA Leased
BS-LEW	Border Station - Lewiston Bridge	ORA	LEWISTON	NY	NORTHEAST-NEWYORK	GSA Leased
BS-MCAL	Border Station - McAllen, TX	ORA	MCALLEN	TX	SOUTHWEST-DALLAS	GSA Leased
BS-MEM	Resident Post - Memphis, TN	ORA	MEMPHIS	TN	SOUTHEAST-ATLANTA	GSA Leased
BS-PEA	Border Station - Peace Bridge	ORA	BUFFALO	NY	NORTHEAST-NEWYORK	GSA Leased
BS-SSMAR	Border Station - Sault Ste Marie, MI	ORA	SAULT STE MARIE	MI	CENTRAL-CHICAGO	GSA Owned
BS-WIL	Resident Post - Wilmington, NC	ORA	WILMINGTON	NC	SOUTHEAST-ATLANTA	GSA Leased
CC-DESM	Daycare - Shared Use	ORA	DES MOINES	IA	SOUTHWEST-DALLAS	GSA Leased
CHUR	Office Of Internal Affairs - OCI Church St	OCI	ROCKVILLE	MD	HEADQUARTERS	GSA Leased
CORP	Corporate Building	CTP	ROCKVILLE	MD	HEADQUARTERS	GSA Leased
CPK1	Harvey W Wiley Building	CFSAN	COLLEGE PARK	MD	HEADQUARTERS	GSA Owned
CPK2	University Station	CFSAN	COLLEGE PARK	MD	HEADQUARTERS	GSA Leased
CRAB	Crabb Building	OC/ORA	ROCKVILLE	MD	HEADQUARTERS	GSA Leased
DDA	Division of Pharmaceutical Analysis - St Louis, MO	CBER	ST LOUIS	MO	HEADQUARTERS-FIELD	GSA Leased
DDA-WULAB	CDER St. Louis Lab at Washington University	CDER	ST LOUIS	MO	HEADQUARTERS-FIELD	GSA Leased
DI-1	Dauphin Island - Seafood Laboratory	CFSAN	DAUPHIN ISLAND	AL	HEADQUARTERS-FIELD	FDA Owned
DI-2	Dauphin Island - Generator Buildings	CFSAN	DAUPHIN ISLAND	AL	HEADQUARTERS-FIELD	FDA Owned
DI-3	Dauphin Island - Outer Buildings	CFSAN	DAUPHIN ISLAND	AL	HEADQUARTERS-FIELD	FDA Owned
DO-ATL	District Office - Regional Office - Atlanta	ORA	ATLANTA	GA	SOUTHEAST-ATLANTA	GSA Leased
DO-BLT	District Office - Baltimore	ORA	BALTIMORE	MD	CENTRAL-PHILADELPHIA	GSA Leased
DO-CHI	District Office - Chicago	ORA	CHICAGO	IL	CENTRAL-CHICAGO	GSA Leased
DO-CIN	District Office - Forensic Chemistry - Cincinnati	ORA	CINCINNATI	OH	CENTRAL-PHILADELPHIA	GSA Leased

*Building ID (FDA-1)	Building Name	FDA Center	City	State	FDA Region Code	Ownership (HHS-15)
DO-DAL	District Office and SW Imports - Dallas	ORA	DALLAS	TX	SOUTHWEST-DALLAS	GSA Leased
DO-DEN	District Office and Lab - Denver	ORA	LAKEWOOD	CO	SOUTHWEST-DALLAS	GSA Owned
DO-DET	District Lab - Detroit	ORA	DETROIT	MI	CENTRAL-CHICAGO	GSA Leased
DO-DET1	District Office - Detroit	ORA	DETROIT	MI	CENTRAL-CHICAGO	GSA Leased
DO-FLA	District Office - Florida - Maitland	ORA	MAITLAND	FL	SOUTHEAST-ATLANTA	GSA Leased
DO-KS	District Office and Lab - Kansas City	ORA	LENEXA	KS	SOUTHWEST-DALLAS	GSA Leased
DO-KS1	District Office Annex - Kansas City	ORA	LENEXA	KS	SOUTHWEST-DALLAS	GSA Leased
DO-KS2	District Office - Kansas City - Lenexa	ORA	LENEXA	KS	SOUTHWEST-DALLAS	GSA Leased
DO-MIN1	District Office - Minneapolis	ORA	MINNEAPOLIS	MN	CENTRAL-CHICAGO	GSA Leased
DO-NSH	District Office - Nashville	ORA	NASHVILLE	TN	SOUTHEAST-ATLANTA	GSA Leased
DO-NWE	District Office - New England	ORA	STONEHAM	MA	NORTHEAST-NEWYORK	GSA Leased
DO-NWJ	District Office - New Jersey	ORA	PARSIPPANY	NJ	CENTRAL-PHILADELPHIA	GSA Leased
DO-NYK	District Office - Regional Office and Lab - New York	ORA	JAMAICA	NY	NORTHEAST-NEWYORK	GSA Leased
DO-PHI	District Office - Regional Office and Lab - Philadelphia	ORA	PHILADELPHIA	PA	CENTRAL-PHILADELPHIA	GSA Owned
DO-SAN	District Office and Lab - San Francisco - Alameda	ORA	ALAMEDA	CA	PACIFIC-OAKLAND	GSA Leased
DO-SEA	District Office and Pacific Regional Lab NW - Seattle	ORA	BOTHELL	WA	PACIFIC-OAKLAND	GSA Owned
DO-SEA1	District Office - Seattle	ORA	BOTHELL	WA	PACIFIC-OAKLAND	GSA Leased
ELEM	Element Building	ORA	ROCKVILLE	MD	HEADQUARTERS	GSA Leased
FHSL	Fishers Lane 5630	CDER/OC	ROCKVILLE	MD	HEADQUARTERS	GSA Leased
FO-CEROC	Central Regional Office - Chicago	OCI	CHICAGO	IL	CENTRAL-CHICAGO	GSA Leased
FO-CHSO	Field Office - OCI Chicago	OCI	LISLE	IL	HEADQUARTERS-FIELD	GSA Leased
FO-GRA	Field Office - OCI Dallas	OCI	GRAPEVINE	TX	SOUTHWEST-DALLAS	GSA Leased
FO-KCSO	Field Office - OCI Kansas City	OCI	MISSION	KS	HEADQUARTERS-FIELD	GSA Leased
FO-MISO	Field Office - OCI Miami	OCI	PLANTATION	FL	HEADQUARTERS-FIELD	GSA Leased
FO-NYSO	Field Office - OCI New York	OCI	JERSEY CITY	NJ	HEADQUARTERS-FIELD	FDA Leased
FO-SDSO	Field Office - OCI Los Angeles	OCI	SAN CLEMENTE	CA	HEADQUARTERS-FIELD	GSA Leased
FO-WASO	Field Office - OCI Washington State	OCI	KIRKLAND	WA	PACIFIC-OAKLAND	GSA Leased
HHSS	Mary E Switzer Building SW	OC	WASHINGTON	DC	HEADQUARTERS	GSA Owned
HILL	Hillandale Building	CDER	SILVER SPRING	MD	HEADQUARTERS	GSA Leased
HR-BETHPL	HR - Bethesda Place	OC	BETHESDA	MD	HEADQUARTERS	GSA Leased
HR-CHI	HR - Chicago	OHR	CHICAGO	IL	CENTRAL-CHICAGO	GSA Leased
HR-NY	HR - New York	OC	NEW YORK	NY	NORTHEAST-NEWYORK	GSA Leased
HR-SF	HR - San Francisco	OC	SAN FRANCISCO	CA	PACIFIC-OAKLAND	GSA Leased
IM-BUF1	Import Office - Buffalo	ORA	BUFFALO	NY	NORTHEAST-NEWYORK	GSA Leased
IRV-1	Los Angeles District Office/Pacific Regional Office and Lab SW - Irvine	ORA	IRVINE	CA	PACIFIC-OAKLAND	FDA Owned
IRV-2	Irvine - Hazmat	ORA	IRVINE	CA	PACIFIC-OAKLAND	FDA Owned

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*Building ID (FDA-1)	Building Name	FDA Center	City	State	FDA Region Code	Ownership (HHS-15)
IRV-3	Irvine - Security Gate House	ORA	IRVINE	CA	PACIFIC-OAKLAND	FDA Owned
MM2	Montrose Metro 2	ORA/CDER/OC	ROCKVILLE	MD	HEADQUARTERS	GSA Leased
MOD1	Muirkirk MOD1 Laboratory	CFSAN	LAUREL	MD	HEADQUARTERS	FDA Owned
MOD2	Muirkirk MOD2 Laboratory - Bldg A	CVM	LAUREL	MD	HEADQUARTERS	GSA Owned
MOFF	Moffett Center	CFSAN	BEDFORD PARK	IL	HEADQUARTERS-FIELD	GSA Leased
MPN1	Metro Park North 1	CVM/CDRH	ROCKVILLE	MD	HEADQUARTERS	GSA Leased
MPN2	Metro Park North 2	OC/OCI/CDER/CVM	ROCKVILLE	MD	HEADQUARTERS	GSA Leased
MPN4	Metro Park North 4	CVM/CDER	ROCKVILLE	MD	HEADQUARTERS	GSA Leased
MPN5	Metro Park North 5	CVM/CDER	ROCKVILLE	MD	HEADQUARTERS	GSA Leased
MPN7	Metro Park North 7	CDER	ROCKVILLE	MD	HEADQUARTERS	GSA Leased
MUIRK-B1	Muirkirk - B1 - Animal Caretakers	CFSAN	LAUREL	MD	HEADQUARTERS	GSA Owned
MUIRK-B2	Muirkirk - B2 - Research Fac Dogs	CFSAN/CDER	LAUREL	MD	HEADQUARTERS	GSA Owned
MUIRK-B3	Muirkirk - B3 - Research Fac Lamb	CFSAN/CDER	LAUREL	MD	HEADQUARTERS	GSA Owned
MUIRK-B4	Muirkirk - B4 - Research Fac-Swin	CFSAN/CDER	LAUREL	MD	HEADQUARTERS	GSA Owned
MUIRK-C1	Muirkirk - C1 - Animal Caretakers	CFSAN/CDER	LAUREL	MD	HEADQUARTERS	GSA Owned
MUIRK-C2	Muirkirk - C2 - 8501 G Muirkirk Rd	CFSAN/CDER	LAUREL	MD	HEADQUARTERS	GSA Owned
MUIRK-C3	Muirkirk - C3 - Research Fac Cows	CFSAN/CDER	LAUREL	MD	HEADQUARTERS	GSA Owned
MUIRK-C4	Muirkirk - C4 - Research Fac-Sheep	CFSAN/CDER	LAUREL	MD	HEADQUARTERS	GSA Owned
MUIRK-C5	Muirkirk - C5 - Research Fac-Cattle	CFSAN/CDER	LAUREL	MD	HEADQUARTERS	GSA Owned
MUIRK-C6	Muirkirk - C6 - Research Fac Cattle	CFSAN/CDER	LAUREL	MD	HEADQUARTERS	GSA Owned
MUIRK-D1	Muirkirk - D1 - 8501 L Muirkirk Rd	CFSAN/CDER	LAUREL	MD	HEADQUARTERS	GSA Owned
MUIRK-D2	Muirkirk - D2 - Feed Mixing	CFSAN/CDER	LAUREL	MD	HEADQUARTERS	GSA Owned
MUIRK-E1	Muirkirk - E1 - Research Fac-Poultry	CFSAN/CDER	LAUREL	MD	HEADQUARTERS	GSA Owned
MUIRK-F1	Muirkirk - F1 - Quarantine	CFSAN/CDER	LAUREL	MD	HEADQUARTERS	GSA Owned
MUIRK-H1	Muirkirk - H - Aquaculture	CFSAN/CDER	LAUREL	MD	HEADQUARTERS	GSA Owned
MUIRK-L	Muirkirk - L - Hay Storage	CFSAN/CDER	LAUREL	MD	HEADQUARTERS	GSA Owned
MUIRK-M	Muirkirk - M - Animal Loafing	CFSAN/CDER	LAUREL	MD	HEADQUARTERS	GSA Owned
MUIRK-PP	Muirkirk - Pasture Pads	CFSAN/CDER	LAUREL	MD	HEADQUARTERS	GSA Owned
MUIRK-T	Muirkirk - T - 8501 T Muirkirk Rd	CFSAN/CDER	LAUREL	MD	HEADQUARTERS	GSA Owned
MUIRK-W	Muirkirk - Waste Storage Area	CFSAN/CDER	LAUREL	MD	HEADQUARTERS	GSA Owned
NCTR-05A	NCTR - Building 5A-Lab - Animal Rooms	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-05B	NCTR - Building 5B - Labs and Admin	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-05B-HM	NCTR - Haz Mat Portable At 5B	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-05C	NCTR - Building 5C - Admin and Computer Center - Storage	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-05D	NCTR - Building 5D - Diet Prep - Lab	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-06	NCTR - Building 6	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned

*Building ID (FDA-1)	Building Name	FDA Center	City	State	FDA Region Code	Ownership (HHS-15)
NCTR-07	NCTR - Building 7 - Boiler Plant	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-09	NCTR - Building 9 - Main Electrical Substation	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-10	NCTR - Building 10 - Library	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-11	NCTR - Building 11 - Water Treatment Plant	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-12	NCTR - Building 12 - Cafeteria and Conference Room	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-13	NCTR - Building 13 - Administrative	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-14A	NCTR - Building 14A - Lab and Animal Holding	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-14B	NCTR - Building 14B - Labs and Animal Holding	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-14C	NCTR - Building 14C - Lab	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-15	NCTR - Building 15 - Admin Office	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-16	NCTR - Building 16 - Paint Shop	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-17	NCTR - Building 17 - Multi-use	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-20	NCTR - Building 20 - Maintenance Building	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-21	NCTR - Building 21 - Security Building	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-26	ORA Regional Laboratory- Arkansas - NCTR - Building 26	ORA	JEFFERSON	AR	SOUTHWEST-DALLAS	FDA Owned
NCTR-28	NCTR - Building 28 - Golf Cart Charging Station	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-31	NCTR - Building 31 - Communications And Copy Center	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-32	NCTR - Building 32 - Storage	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-37	NCTR - Building 37 - Hazardous Storage	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-44	NCTR - Building 44 - Waste Water Treatment	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-45	NCTR - Building 45 - Maintenance	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-46	NCTR - Building 46 - Incinerator	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-50	NCTR - Building 50 - Main Administration	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-51	NCTR - Building 51 - Labs	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-52	NCTR - Building 52 - Warehouse	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-53A	NCTR - Building 53A - Labs and Animals	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-53B	NCTR - Building 53B - Labs and Animals	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-53C	NCTR - Building 53C - Labs and Animals	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-53C-HM	NCTR - Haz Mat Portable At 53C	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-53D	NCTR - Building 53D - Labs and Animals	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-53E	NCTR - Building 53E - Labs	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-54	NCTR - Building 54 - Occup Health EMCS	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-58	NCTR - Building 58 - Main Corridors - storage	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-58B	NCTR - Building 58B - Connecting Corridors	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-60	NCTR - Building 60 - Microbiology Labs	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-62	NCTR - Building 62 - Labs, BSL and Primates	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned

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*Building ID (FDA-1)	Building Name	FDA Center	City	State	FDA Region Code	Ownership (HHS-15)
NCTR-70	NCTR - Building 70 - Common - Conference Room	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-71	NCTR - Building 71 - Residence - Dormitories	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-72	NCTR - Building 72 - Residence - Dormitories	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-73	NCTR - Building 73 - Residence - Dormitories	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-74	NCTR - Building 74 - Residence - Dormitories	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-85A	NCTR - Building 85A - Warehouse and Laundry	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-85B	NCTR - Building 85B - Storage	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-85C	NCTR - Building 85C - Storage	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-P01	NCTR - Guard Portable Shed Delivery	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-P19	NCTR - Guard Portable Shed Roadway	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-T05	NCTR - Building T-5 - Office Trailer	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-T45	NCTR - Building T-45 - Modular Offices - Facility Maint Contractor	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NLRC	Nicholson Lane Research Center	CBER	KENSINGTON	MD	HEADQUARTERS	GSA Leased
NLRC-D	Nicholson Lane Research Center	CBER	KENSINGTON	MD	HEADQUARTERS	FDA Leased
OAK4	Oakgrove Building - 2094 Gaither	CDRH	ROCKVILLE	MD	HEADQUARTERS	GSA Leased
OAK8	Oakgrove Building - 2098 Gaither	CDRH	ROCKVILLE	MD	HEADQUARTERS	GSA Leased
PIFO	Piccard Building 1350	CDRH/ORA	ROCKVILLE	MD	HEADQUARTERS	GSA Leased
PRK-ATL	Parking - Atlanta, GA - OCI	OCI	ATLANTA	GA	SOUTHEAST-ATLANTA	GSA Owned
PRK-BUF	Parking - Buffalo Niagara Center	ORA	BUFFALO	NY	NORTHEAST-NEWYORK	GSA Leased
PRK-CHI	Parking - Union Station	ORA	CHICAGO	IL	CENTRAL-CHICAGO	GSA Leased
PRK-COL	Parking Garage - MJ Perry Jr	ORA	COLUMBIA	SC	SOUTHEAST-ATLANTA	GSA Owned
PRK-DM	Parking - Ampco System Parking	ORA	DES MOINES	IA	SOUTHWEST-DALLAS	GSA Leased
PRK-FTM	Parking - City of Palms Garage	ORA	FORT MYERS	FL	SOUTHEAST-ATLANTA	GSA Leased
PRK-JAC	Parking Garage - JRA Facility No 3	ORA	JACKSON	MS	SOUTHEAST-ATLANTA	GSA Leased
PRK-OKL	Parking Garage - OKC Federal	ORA	OKLAHOMA CITY	OK	SOUTHWEST-DALLAS	GSA Owned
PRK-PHIL	Parking - PHIL Parking Authority Garage	ORA	PHILADELPHIA	PA	CENTRAL-PHILADELPHIA	GSA Leased
PRK-RAL1	Parking - Terry Sanford Federal Building	ORA	RALEIGH	NC	SOUTHEAST-ATLANTA	GSA Owned
PRK-RAL2	Parking Deck - Moore Square	ORA	RALEIGH	NC	SOUTHEAST-ATLANTA	GSA Leased
PRK-SUN	Parking - Sunrise, FL - OCI	OCI	PLANTATION	FL	SOUTHEAST-ATLANTA	GSA Leased
PRK-WOG1	Parking - White Oak Southwest Parking Garage	CDER/OC/CDRH	SILVER SPRING	MD	HEADQUARTERS	GSA Owned
PRK-WOG2	Parking - White Oak Northeast Parking Garage	CDER/OC/CDRH	SILVER SPRING	MD	HEADQUARTERS	GSA Owned
PRK-WOG3	Parking - White Oak North Parking Garage	CDER/OC/CDRH	SILVER SPRING	MD	HEADQUARTERS	GSA Owned
RKW2	Rockwall II Building	CBER/CDER	ROCKVILLE	MD	HEADQUARTERS	GSA Leased
RKWL	Rockwall Building	CBER	ROCKVILLE	MD	HEADQUARTERS	GSA Leased
RL-SE	Regional Laboratory - Southeast Atlanta Annex II	ORA	ATLANTA	GA	SOUTHEAST-ATLANTA	GSA Leased
RO-BORO1	Resident Office - OCI Wakefield, MA	OCI	WAKEFIELD	MA	NORTHEAST-NEWYORK	GSA Leased

*Building ID (FDA-1)	Building Name	FDA Center	City	State	FDA Region Code	Ownership (HHS-15)
RO-DAL	Regional Office - Dallas, TX	ORA	DALLAS	TX	SOUTHWEST-DALLAS	GSA Leased
RO-GARO	Resident Office - OCI Atlanta	OCI	ATLANTA	GA	HEADQUARTERS-FIELD	GSA Owned
RO-NORO	Resident Office - OCI New Orleans	OCI	COVINGTON	LA	HEADQUARTERS-FIELD	GSA Leased
RO-P	Pacific Regional Office - Oakland	ORA	OAKLAND	CA	PACIFIC-OAKLAND	GSA Owned
RO-PH	Resident Office - OCI Phoenix	OCI	PHOENIX	AZ	HEADQUARTERS-FIELD	GSA Leased
RO-SFRO	Resident Office - OCI San Francisco	OCI	OAKLAND	CA	HEADQUARTERS-FIELD	GSA Leased
RO-SJRO	Resident Office - OCI San Juan	OCI	SAN JUAN	PR	HEADQUARTERS-FIELD	GSA Leased
RO-TXRO	Resident Office - OCI Austin	OCI	AUSTIN	TX	HEADQUARTERS-FIELD	GSA Leased
RP-ABQ	Resident Post - Albuerque, NM	ORA	ALBUQUERQUE	NM	SOUTHWEST-DALLAS	GSA Leased
RP-ABY2	Border Station - Alexandria Bay, NY	ORA	ALEXANDRIA BAY	NY	NORTHEAST-NEWYORK	GSA Owned
RP-AGU	Resident Post - Aguada, PR	ORA	AGUADA	PR	SOUTHEAST-ATLANTA	GSA Leased
RP-ALB	Resident Post - Albany, NY	ORA	ALBANY	NY	NORTHEAST-NEWYORK	GSA Leased
RP-ANCH	Resident Post - Anchorage, AK	ORA	ANCHORAGE	AK	PACIFIC-OAKLAND	GSA Owned
RP-ARD	Resident Post - Arden, NC	ORA	ARDEN	NC	SOUTHEAST-ATLANTA	GSA Leased
RP-AUG	Resident Post - Augusta, Me	ORA	AUGUSTA	ME	NORTHEAST-NEWYORK	GSA Leased
RP-AUS1	Resident Post - Austin, TX	ORA	AUSTIN	TX	SOUTHWEST-DALLAS	GSA Leased
RP-BCR1	Resident Post - Boca Raton, FL - Atrium Financial Center	ORA	BOCA RATON	FL	SOUTHEAST-ATLANTA	GSA Leased
RP-BEN	Resident Post - Bensenville, IL	ORA	BENSENVILLE	IL	CENTRAL-CHICAGO	GSA Leased
RP-BIN	Resident Post - Binghamton, NY	ORA	BINGHAMTON	NY	NORTHEAST-NEWYORK	GSA Owned
RP-BIR	Resident Post - Birmingham, AL	ORA	BIRMINGHAM	AL	SOUTHEAST-ATLANTA	GSA Leased
RP-BLA	Border Station - Blaine, WA - Breezeway	ORA	BLAINE	WA	PACIFIC-OAKLAND	GSA Owned
RP-BLA1	Border Station - Blaine, WA - Cargo	ORA	BLAINE	WA	PACIFIC-OAKLAND	GSA Owned
RP-BOI1	Resident Post - Boise, ID - Mclure Federal Bulding	ORA	BOISE	ID	PACIFIC-OAKLAND	GSA Leased
RP-BOY	Resident Post - Boylston, MA	ORA	BOYLSTON	MA	NORTHEAST-NEWYORK	GSA Leased
RP-BRD	Resident Post - Bridgeport, CT	ORA	BRIDGEPORT	CT	NORTHEAST-NEWYORK	GSA Owned
RP-BRN	Resident Post - Brunswick, OH	ORA	BRUNSWICK	OH	CENTRAL-PHILADELPHIA	GSA Leased
RP-BRV	Border Station - Brownsville, TX	ORA	BROWNSVILLE	TX	SOUTHWEST-DALLAS	GSA Owned
RP-BTA	Border Station - Bota, TX - Bridge of the America's	ORA	EL PASO	TX	SOUTHWEST-DALLAS	GSA Owned
RP-BTR1	Resident Post - Baton Rouge, LA - Citiplace Centre	ORA	BATON ROUGE	LA	SOUTHEAST-ATLANTA	GSA Leased
RP-CALX	Border Station - Calexico, CA - Modular Bldg	ORA	CALEXICO	CA	PACIFIC-OAKLAND	GSA Owned
RP-CHG	Resident Post - Chattanooga, TN	ORA	CHATTANOOGA	TN	SOUTHEAST-ATLANTA	GSA Leased
RP-CHP3	Resident Post - Champlain NY - Cargo Building	ORA	CHAMPLAIN	NY	NORTHEAST-NEWYORK	GSA Owned
RP-CHR	Resident Post - Charleston, SC	ORA	CHARLESTON	SC	SOUTHEAST-ATLANTA	GSA Leased
RP-CHT	Resident Post - Charlotte, NC	ORA	CHARLOTTE	NC	SOUTHEAST-ATLANTA	GSA Leased
RP-CIN	Resident Post - Cincinnati, OH	ORA	CINCINNATI	OH	CENTRAL-PHILADELPHIA	GSA Leased
RP-CLX	Border Station - Calexico, CA - Import Bldg	ORA	CALEXICO	CA	PACIFIC-OAKLAND	GSA Leased

*Building ID (FDA-1)	Building Name	FDA Center	City	State	FDA Region Code	Ownership (HHS-15)
RP-CNP2	Resident Post - Los Angeles, CA	ORA	WOODLAND HILLS	CA	PACIFIC-OAKLAND	GSA Leased
RP-COB1	Resident Post - Columbia, SC	ORA	COLUMBIA	SC	SOUTHEAST-ATLANTA	GSA Owned
RP-COL1	Resident Post - Columbus, OH	ORA	COLUMBUS	OH	CENTRAL-PHILADELPHIA	GSA Leased
RP-CON	Resident Post - Concord, NH	ORA	CONCORD	NH	NORTHEAST-NEWYORK	GSA Owned
RP-COV	Resident Post - Covington, LA - Resource Bank Building	ORA	COVINGTON	LA	SOUTHEAST-ATLANTA	GSA Leased
RP-DAV	Resident Post - Davenport, IA	ORA	DAVENPORT	IA	SOUTHWEST-DALLAS	GSA Leased
RP-DEM	Resident Post - Des Moines, IA	ORA	DES MOINES	IA	SOUTHWEST-DALLAS	GSA Owned
RP-DEN	Resident Post - Denver Airport, Denver, CO	ORA	DENVER	CO	SOUTHWEST-DALLAS	GSA Leased
RP-DET	Border Station - Detroit, MI	ORA	DETROIT	MI	CENTRAL-CHICAGO	GSA Owned
RP-DMT	Resident Post - Dundalk, MD - Import	ORA	BALTIMORE	MD	CENTRAL-PHILADELPHIA	GSA Leased
RP-EBR	Resident Post - East Brunswick, NJ	ORA	EAST BRUNSWICK	NJ	CENTRAL-PHILADELPHIA	GSA Leased
RP-EGL	Border Station - Eagle Pass, TX	ORA	EAGLE PASS	TX	SOUTHWEST-DALLAS	GSA Leased
RP-ELP	Resident Post - El Paso, TX	ORA	EL PASO	TX	SOUTHWEST-DALLAS	GSA Owned
RP-ELP1	Resident Post - El Paso, TX	ORA	EL PASO	TX	SOUTHWEST-DALLAS	GSA Leased
RP-ELZ	Resident Post - Elizabeth, NJ	ORA	ELIZABETH	NJ	CENTRAL-PHILADELPHIA	GSA Leased
RP-ETP	Border Station - Eastport, ID	ORA	EASTPORT	ID	PACIFIC-OAKLAND	GSA Owned
RP-EVN	Resident Post - Evansville, IN	ORA	EVANSVILLE	IN	CENTRAL-CHICAGO	GSA Leased
RP-FRE	Resident Post - Fresno, CA	ORA	FRESNO	CA	PACIFIC-OAKLAND	GSA Leased
RP-FRG	Resident Post - Fargo, ND	ORA	FARGO	ND	CENTRAL-CHICAGO	GSA Owned
RP-FTM1	Resident Post - Fort Myers, FL	ORA	FORT MYERS	FL	SOUTHEAST-ATLANTA	GSA Owned
RP-FTW	Resident Post - Fort Worth, TX	ORA	FORT WORTH	TX	SOUTHWEST-DALLAS	GSA Owned
RP-FWN	Resident Post - Standard Federal Plaza, Fort Wayne, IN	ORA	FORT WAYNE	IN	CENTRAL-CHICAGO	GSA Leased
RP-GNB	Resident Post - Green Bay, WI	ORA	GREEN BAY	WI	CENTRAL-CHICAGO	GSA Leased
RP-GRN	Resident Post - Greenville, NC	ORA	GREENVILLE	NC	SOUTHEAST-ATLANTA	GSA Leased
RP-GRO	Resident Post - Greensboro, NC	ORA	GREENSBORO	NC	SOUTHEAST-ATLANTA	GSA Leased
RP-GRP	Resident Post - Grand Rapids, MI	ORA	GRAND RAPIDS	MI	CENTRAL-CHICAGO	GSA Leased
RP-GRV	Resident Post - Greenville, SC	ORA	GREENVILLE	SC	SOUTHEAST-ATLANTA	GSA Leased
RP-GUR	Resident Post - Gurnee, IL	ORA	GURNEE	IL	CENTRAL-CHICAGO	GSA Leased
RP-HAR	Resident Post - Harrisburg, PA	ORA	HARRISBURG	PA	CENTRAL-PHILADELPHIA	GSA Leased
RP-HEL	Resident Post - Helena MT	ORA	HELENA	MT	PACIFIC-OAKLAND	GSA Leased
RP-HIN	Resident Post - Hinsdale, IL	ORA	HINSDALE	IL	CENTRAL-CHICAGO	GSA Leased
RP-HLW	Resident Post - Hollywood, FL	ORA	HOLLYWOOD	FL	SOUTHEAST-ATLANTA	GSA Leased
RP-HON	Resident Post - Honolulu, HI	ORA	HONOLULU	HI	PACIFIC-OAKLAND	GSA Owned
RP-HOU2	Resident Post - Houston, TX	ORA	HOUSTON	TX	SOUTHWEST-DALLAS	GSA Leased
RP-HOU3	Resident Post - Houston, TX - Federal Reserve Bank of Dallas/Houston Br	ORA	HOUSTON	TX	SOUTHWEST-DALLAS	GSA Leased
RP-HRT	Resident Post - Hartford, CT	ORA	HARTFORD	CT	NORTHEAST-NEWYORK	GSA Owned

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RP-IND	Resident Post - Indianapolis, IN	ORA	INDIANAPOLIS	IN	CENTRAL-CHICAGO	GSA Leased
RP-INF2	Resident Post - International Falls, MN	ORA	INTERNATIONAL FALLS	MN	CENTRAL-CHICAGO	GSA Leased
RP-JKS	Resident Post - Jackson, MS	ORA	JACKSON	MS	SOUTHEAST-ATLANTA	GSA Owned
RP-JKV	Resident Post - Jacksonville, FL	ORA	JACKSONVILLE	FL	SOUTHEAST-ATLANTA	GSA Leased
RP-KAL	Resident Post - Kalamazoo, MI	ORA	KALAMAZOO	MI	CENTRAL-CHICAGO	GSA Owned
RP-KNX	Resident Post - Knoxville, TN	ORA	KNOXVILLE	TN	SOUTHEAST-ATLANTA	GSA Leased
RP-LAFA	Resident Post - Lafayette, LA	ORA	LAFAYETTE	LA	SOUTHEAST-ATLANTA	GSA Owned
RP-LAR	Border Station - Laredo, TX - USBS Columbia Import Dock	ORA	LAREDO	TX	SOUTHWEST-DALLAS	GSA Owned
RP-LAR1	Border Station - Laredo, TX - USBS J&L Bridge 2, Bldg 2	ORA	LAREDO	TX	SOUTHWEST-DALLAS	GSA Owned
RP-LAR2	Border Station - Laredo, TX - USBS World Trade Import Dock	ORA	LAREDO	TX	SOUTHWEST-DALLAS	GSA Owned
RP-LAX3	Resident Post - El Segundo at North Sepulveda Blvd	ORA	EL SEGUNDO	CA	PACIFIC-OAKLAND	GSA Leased
RP-LI	Resident Post - Long Island, NY	ORA	CENTRAL ISLIP	NY	NORTHEAST-NEWYORK	GSA Owned
RP-LRK	Resident Post - Little Rock, AR	ORA	LITTLE ROCK	AR	SOUTHWEST-DALLAS	GSA Owned
RP-LSV	Resident Post - Louisville, KY	ORA	LOUISVILLE	KY	CENTRAL-PHILADELPHIA	GSA Leased
RP-LTS	Border Station - Los Tomates, TX	ORA	BROWNSVILLE	TX	SOUTHWEST-DALLAS	GSA Owned
RP-LVG	Resident Post - Las Vegas, NV	ORA	LAS VEGAS	NV	PACIFIC-OAKLAND	GSA Owned
RP-MAD	Resident Post - Madison, WI	ORA	MADISON	WI	CENTRAL-CHICAGO	GSA Leased
RP-MAS2	Border Station - Massena, NY - Port of Massena	ORA	MASSENA	NY	NORTHEAST-NEWYORK	GSA Owned
RP-MEM	Resident Post - Memphis, TN	ORA	MEMPHIS	TN	SOUTHEAST-ATLANTA	GSA Leased
RP-MET	Resident Post - Metairie Center	ORA	METAIRIE	LA	SOUTHEAST-ATLANTA	GSA Leased
RP-MGN	Resident Post - Morgantown, WV	ORA	MORGANTOWN	WV	CENTRAL-PHILADELPHIA	GSA Leased
RP-MIA1	Resident Post - Miami, FL- Domestic	ORA	MIAMI	FL	SOUTHEAST-ATLANTA	GSA Leased
RP-MIA3	Resident Post - Miami, FL - USPS Mail Facility	ORA	MIAMI	FL	SOUTHEAST-ATLANTA	GSA Leased
RP-MOB	Resident Post - Mobile, AL	ORA	MOBILE	AL	SOUTHEAST-ATLANTA	GSA Leased
RP-MTG2	Resident Post - Sterling Centre	ORA	MONTGOMERY	AL	SOUTHEAST-ATLANTA	GSA Leased
RP-MVN	Resident Post - Mount Vernon, IL	ORA	MT VERNON	IL	CENTRAL-CHICAGO	GSA Owned
RP-NOG	Border Station - Nogales, AZ - N Frank Reed	ORA	NOGALES	AZ	SOUTHWEST-DALLAS	GSA Leased
RP-NOG2	Border Station - Nogales, AZ - Truck Compound	ORA	NOGALES	AZ	SOUTHWEST-DALLAS	GSA Owned
RP-NOVA	Resident Post - Falls Church, VA	ORA	FALLS CHURCH	VA	CENTRAL-PHILADELPHIA	GSA Leased
RP-NWW	Resident Post - New Windsor, NY	ORA	NEW WINDSOR	NY	NORTHEAST-NEWYORK	GSA Leased
RP-OGD	Border Station - Ogdensburg, NY	ORA	OGDENSBURG	NY	NORTHEAST-NEWYORK	GSA Leased
RP-OKL	Resident Post - Oklahoma City, OK	ORA	OKLAHOMA CITY	OK	SOUTHWEST-DALLAS	GSA Owned
RP-OMH1	Resident Post - Omaha, NE - Empire Court	ORA	OMAHA	NE	SOUTHWEST-DALLAS	GSA Leased
RP-ONT	Resident Post - Ontario, CA	ORA	ONTARIO	CA	PACIFIC-OAKLAND	GSA Leased
RP-OROV	Resident Post - Oroville, WA	ORA	OROVILLE	WA	PACIFIC-OAKLAND	GSA Owned
RP-OTA	Border Station - Otay Mesa, CA - Via De La Amistad	ORA	SAN DIEGO	CA	PACIFIC-OAKLAND	GSA Owned

*Building ID (FDA-1)	Building Name	FDA Center	City	State	FDA Region Code	Ownership (HHS-15)
RP-OTA1	Border Station - Otay Mesa, CA - Otay Professional Bldg	ORA	OTAY	CA	PACIFIC-OAKLAND	GSA Leased
RP-PDX	Resident Post - Portland Airport, OR	ORA	PORTLAND	OR	PACIFIC-OAKLAND	GSA Leased
RP-PEM	Border Station - Pembina, ND	ORA	PEMBINA	ND	CENTRAL-CHICAGO	GSA Leased
RP-PEO1	Resident Post - Peoria, IL	ORA	PEORIA	IL	CENTRAL-CHICAGO	GSA Leased
RP-PER	Resident Post - Perrysburg, OH	ORA	PERRYSBURG	OH	CENTRAL-PHILADELPHIA	GSA Leased
RP-PHIL	Field Office - OCI Philadelphia	OCI	PHILADELPHIA	PA	CENTRAL-PHILADELPHIA	GSA Leased
RP-PHR	Border Station - Pharr, TX - Import Dock	ORA	PHARR	TX	SOUTHWEST-DALLAS	GSA Owned
RP-PHRR	Border Station - Pharr, TX - Modular Bldg	ORA	PHARR	TX	SOUTHWEST-DALLAS	GSA Owned
RP-PHX	Resident Post - Phoenix, AZ	ORA	TEMPE	AZ	SOUTHWEST-DALLAS	GSA Leased
RP-PIT	Resident Post - Pittsburgh, PA	ORA	PITTSBURGH	PA	CENTRAL-PHILADELPHIA	GSA Leased
RP-PON	Resident Post - Ponce, PR	ORA	PONCE	PR	SOUTHEAST-ATLANTA	GSA Leased
RP-PORT	Resident Post - Portsmouth, VA - Mast One	ORA	PORTSMOUTH	VA	CENTRAL-PHILADELPHIA	GSA Leased
RP-PROV	Field Office - OCI Providence, RI	OCI	NORTH PROVIDENCE	RI	NORTHEAST-NEWYORK	GSA Leased
RP-PRV1	Resident Post - Providence, RI	ORA	EAST PROVIDENCE	RI	NORTHEAST-NEWYORK	GSA Leased
RP-PS	Resident Post - Seattle, WA	ORA	SEATTLE	WA	PACIFIC-OAKLAND	GSA Leased
RP-PTLD	Resident Post - Beaverton, OR	ORA	BEAVERTON	OR	PACIFIC-OAKLAND	GSA Leased
RP-RAL	Resident Post - Raleigh, NC	ORA	RALEIGH	NC	SOUTHEAST-ATLANTA	GSA Owned
RP-RCH	Resident Post - Richmond, VA	ORA	RICHMOND	VA	CENTRAL-PHILADELPHIA	GSA Leased
RP-REN	Resident Post - Reno, NV	ORA	RENO	NV	PACIFIC-OAKLAND	GSA Owned
RP-RGC	Border Station - Rio Grande City, TX	ORA	RIO GRANDE CITY	TX	SOUTHWEST-DALLAS	GSA Leased
RP-RNK	Resident Post - Roanoke VA	ORA	ROANOKE	VA	CENTRAL-PHILADELPHIA	GSA Leased
RP-ROC	Resident Post - Rochester, NY	ORA	ROCHESTER	NY	NORTHEAST-NEWYORK	GSA Leased
RP-SA	Resident Post - San Antonio, TX	ORA	SAN ANTONIO	TX	SOUTHWEST-DALLAS	GSA Leased
RP-SAC	Resident Post - Sacramento, CA	ORA	SACRAMENTO	CA	PACIFIC-OAKLAND	GSA Owned
RP-SAO	Resident Post - San Diego, CA	ORA	SAN DIEGO	CA	PACIFIC-OAKLAND	GSA Leased
RP-SAV1	Resident Post - Savannah, Ga - Johnson Square Business Center	ORA	SAVANNAH	GA	SOUTHEAST-ATLANTA	GSA Leased
RP-SBD	Resident Post - South Bend, IN	ORA	SOUTH BEND	IN	CENTRAL-CHICAGO	GSA Leased
RP-SFX	Resident Post - San Francisco Airport, CA	ORA	SAN FRANCISCO	CA	PACIFIC-OAKLAND	GSA Leased
RP-SFX2	Resident Post - San Francisco at Oyster Point	ORA	SAN FRANCISCO	CA	PACIFIC-OAKLAND	GSA Leased
RP-SHV	Resident Post - Shreveport, LA	ORA	SHREVEPORT	LA	SOUTHEAST-ATLANTA	GSA Leased
RP-SJO	Resident Post - San Jose, CA	ORA	SAN JOSE	CA	PACIFIC-OAKLAND	GSA Leased
RP-SLB	Resident Post - St Louis, MO	ORA	MAPLEWOOD	MO	SOUTHWEST-DALLAS	GSA Leased
RP-SLC	Resident Post - Salt Lake City, UT	ORA	SALT LAKE CITY	UT	SOUTHWEST-DALLAS	GSA Leased
RP-SNL3	Commercial Inspection Building - San Luis, AZ	ORA	SAN LUIS	AZ	SOUTHWEST-DALLAS	GSA Owned
RP-SNT2	Border Station - Santa Teresa, NM	ORA	SANTA TERESA	NM	SOUTHWEST-DALLAS	GSA Owned
RP-SPD	Resident Post - San Pedro, CA	ORA	SAN PEDRO	CA	PACIFIC-OAKLAND	GSA Leased

*Building ID (FDA-1)	Building Name	FDA Center	City	State	FDA Region Code	Ownership (HHS-15)
RP-SPG	Resident Post - Springfield, MO	ORA	SPRINGFIELD	MO	SOUTHWEST-DALLAS	GSA Leased
RP-SPO1	Resident Post - Spokane Valley, WA	ORA	SPOKANE VALLEY	WA	PACIFIC-OAKLAND	GSA Leased
RP-SPR	Resident Post - Springfield, IL	ORA	SPRINGFIELD	IL	CENTRAL-CHICAGO	GSA Leased
RP-STO1	Resident Post - Stockton, CA	ORA	STOCKTON	CA	PACIFIC-OAKLAND	GSA Leased
RP-STOM	Resident Post - St Thomas, VI	ORA	ST. THOMAS	VI	SOUTHEAST-ATLANTA	GSA Leased
RP-SWG	Border Station - Sweetgrass, Mt	ORA	SWEETGRASS	MT	PACIFIC-OAKLAND	GSA Owned
RP-SXF	Resident Post - Sioux Falls, SD	ORA	SIOUX FALLS	SD	CENTRAL-CHICAGO	GSA Leased
RP-SYR1	Resident Post - Syracuse, NY	ORA	SYRACUSE	NY	NORTHEAST-NEWYORK	GSA Leased
RP-TAC	Resident Post - Tacoma, WA	ORA	TACOMA	WA	PACIFIC-OAKLAND	GSA Leased
RP-TAL1	Resident Post - Tallahassee, FL	ORA	TALLAHASSEE	FL	SOUTHEAST-ATLANTA	GSA Leased
RP-TEC	Border Station - Tecate, CA	ORA	TECATE	CA	PACIFIC-OAKLAND	GSA Owned
RP-TIF	Resident Post - Tifton, GA	ORA	TIFTON	GA	SOUTHEAST-ATLANTA	GSA Leased
RP-TMP1	Resident Post - Tampa, FL	ORA	TAMPA	FL	SOUTHEAST-ATLANTA	GSA Leased
RP-TUL2	Resident Post - Tulsa, OK	ORA	TULSA	OK	SOUTHWEST-DALLAS	GSA Leased
RP-TUS	Resident Post - Tucson, AZ	ORA	TUCSON	AZ	SOUTHWEST-DALLAS	GSA Owned
RP-VHS	Resident Post - Voorhees, NJ	ORA	VOORHEES	NJ	CENTRAL-PHILADELPHIA	GSA Leased
RP-WAU	Resident Post - Wauwatosa, WI	ORA	WAUWATOSA	WI	CENTRAL-CHICAGO	GSA Leased
RP-WBAR	Resident Post - Wilkes Barre, PA	ORA	WILKES BARRE	PA	CENTRAL-PHILADELPHIA	GSA Leased
RP-WHP	Resident Post - White Plains, NY	ORA	WHITE PLAINS	NY	NORTHEAST-NEWYORK	GSA Leased
RP-WIC1	Resident Post - Wichita, KS	ORA	WICHITA	KS	SOUTHWEST-DALLAS	GSA Leased
RP-WIL	Resident Post - Wilmington, DE	ORA	WILMINGTON	DE	CENTRAL-PHILADELPHIA	GSA Leased
RP-YSL	Border Station - Ysletta, TX	ORA	EL PASO	TX	SOUTHWEST-DALLAS	GSA Owned
RPHR-ATL	Resident Post - HR - Atlanta, GA		COLLEGE PARK	GA	SOUTHEAST-ATLANTA	GSA Leased
SJN-DO	San Juan - FDA Laboratory Building	ORA	SAN JUAN	PR	SOUTHEAST-ATLANTA	FDA Owned
SJN-DO1	San Juan - New Administration Building - TORO Building	ORA	SAN JUAN	PR	SOUTHEAST-ATLANTA	FDA Owned
SJN-DO2	San Juan - Administration Building	ORA	SAN JUAN	PR	SOUTHEAST-ATLANTA	FDA Owned
SJN-DO3	San Juan - Conference Building	ORA	SAN JUAN	PR	SOUTHEAST-ATLANTA	FDA Owned
SJN-DO4	San Juan - Maintenance Building	ORA	SAN JUAN	PR	SOUTHEAST-ATLANTA	FDA Owned
SJN-DO5	San Juan - Generator Building	ORA	SAN JUAN	PR	SOUTHEAST-ATLANTA	FDA Owned
SJN-DO6	San Juan - Boat House Building	ORA	SAN JUAN	PR	SOUTHEAST-ATLANTA	FDA Owned
SJN-DO7	San Juan - Guard Booth	ORA	SAN JUAN	PR	SOUTHEAST-ATLANTA	FDA Owned
SPS	OCI Task Force Beltsville, MD - Special Prosecution Staff	OCI	BELTSVILLE	MD	HEADQUARTERS	GSA Leased
TECH	Technology Center	CDRH/OC	GAITHERSBURG	MD	HEADQUARTERS	GSA Leased
WARE	FDA Warehouse - Parklawn Drive	OC/CBER	ROCKVILLE	MD	HEADQUARTERS	GSA Leased
WEAC	WEAC Engineering And Analytical Center	ORA	WINCHESTER	MA	NORTHEAST-NEWYORK	FDA Owned
WEAC-1	WEAC- Storage Warehouse 7	ORA	WINCHESTER	MA	NORTHEAST-NEWYORK	FDA Owned

*Building ID (FDA-1)	Building Name	FDA Center	City	State	FDA Region Code	Ownership (HHS-15)
WEAC-2	WEAC- Old Mouse House	ORA	WINCHESTER	MA	NORTHEAST-NEWYORK	FDA Owned
WEAC-3	WEAC - Storage Warehouse 1	ORA	WINCHESTER	MA	NORTHEAST-NEWYORK	FDA Owned
WEAC-4	WEAC- Fire Extinguisher Shed	ORA	WINCHESTER	MA	NORTHEAST-NEWYORK	FDA Owned
WEAC-5	WEAC - Hazmat Trailer 1	ORA	WINCHESTER	MA	NORTHEAST-NEWYORK	FDA Owned
WEAC-6	WEAC - Hazmat Trailer 2	ORA	WINCHESTER	MA	NORTHEAST-NEWYORK	FDA Owned
WEAC-7	WEAC - Hazmat Building	ORA	WINCHESTER	MA	NORTHEAST-NEWYORK	FDA Owned
WEAC-8	WEAC - Freezer 1	ORA	WINCHESTER	MA	NORTHEAST-NEWYORK	FDA Owned
WEAC-9	WEAC - Freezer 2	ORA	WINCHESTER	MA	NORTHEAST-NEWYORK	FDA Owned
WO-CDER 1	White Oak CDER Office Building 1	OC/CDER/CDRH	SILVER SPRING	MD	HEADQUARTERS	GSA Owned
WO-LSB	White Oak Life Sciences Building	CDER/CDRH	SILVER SPRING	MD	HEADQUARTERS	GSA Owned
WO1	White Oak Building 1	OC	SILVER SPRING	MD	HEADQUARTERS	GSA Owned
WO110	White Oak Building 110 - Child Care		SILVER SPRING	MD	HEADQUARTERS	GSA Owned
WO130	White Oak Building 130	CDRH	SILVER SPRING	MD	HEADQUARTERS	GSA Owned
WO2	White Oak Building 2	OC	SILVER SPRING	MD	HEADQUARTERS	GSA Owned
WO31	White Oak Building 31	CDER/OC/ORA	SILVER SPRING	MD	HEADQUARTERS	GSA Owned
WO32	White Oak Building 32	OC	SILVER SPRING	MD	HEADQUARTERS	GSA Owned
WO51	White Oak Building 51	CDER	SILVER SPRING	MD	HEADQUARTERS	GSA Owned
WO62	White Oak Building 62	CDRH/OC	SILVER SPRING	MD	HEADQUARTERS	GSA Owned
WO66	White Oak Building 66	CDRH/OC	SILVER SPRING	MD	HEADQUARTERS	GSA Owned
WOC1	Woodmont Office Center	CBER	ROCKVILLE	MD	HEADQUARTERS	GSA Leased
WOC2	Woodmont Place	CBER	ROCKVILLE	MD	HEADQUARTERS	GSA Leased

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Food and Drug Administration
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House Significant Items
Contained in House Report 112-542
June 19, 2012

Item 1 – Spending Plans – Within 30 days from the enactment of this Act, the Commissioner shall notify the Committees on Appropriations of both Houses of Congress, on the allocation of the funds provided herein by account, and within each account by program, project and activity.

FDA Action
FDA will provide the report that the Committee requested.

Item 2 – Bacterial Contamination of Blood –The Committee is aware that bacterial contamination of blood platelets is a risk for blood transfusion recipients. The Committee also is aware of a recent study that showed the vast majority of bacterially contaminated platelets are being missed by culture testing and that bacterial testing of platelets on the day of transfusion using an existing FDA approved technology may be beneficial to some transfusion recipients. The Committee directs FDA to provide a report to the Committees on Appropriations of both Houses of Congress, within 90 days of enactment of this Act, on the need to make the medical community aware of the safety risks to transfusion patients from bacterially contaminated platelets and to determine what further actions FDA should take to reduce the risk of this type of infection.

FDA Action
FDA will provide the report that the Committee requested.

Item 3 – Seafood Advisory – The Committee is concerned that FDA has not published a final seafood advisory as directed in House Report 112-101 and Senate Report 112-73. The Committee directs FDA to issue a final seafood advisory consistent with USDA's dietary guidelines by July 31, 2012. The Committee directs the FDA Commissioner to notify the Committee in writing prior to this date if this directive will not be met and include the reasons for not meeting it.

FDA Action
FDA began reconsideration of its 2004 seafood advisory regarding the nutritional value of seafood consumption during pregnancy, in consultation with the Environmental Protection Agency (EPA), in 2011. FDA and EPA are working to issue updated seafood consumption advice.

Item 4 – Global Health –The Committee recognizes the critical contribution that FDA's global health research, development funding, and leadership in licensing health technologies make to improve global health. The Committee also recognizes the need to sustain and support U.S. investment in this area by providing funding to FDA to carry out this work. The Committee directs FDA to submit a report to the Committees on Appropriations of the House of Representatives and the Senate, within 60 days of enactment of this Act, outlining the implementation of the findings and recommendations in the Report to Congress referred to in paragraphs (2) and (3) of section 740(c) of Public Law 111-80. The Committee also urges FDA to make the necessary modifications to include Chagas disease in its list of neglected diseases in line with the World Health Organization list of neglected and tropical diseases.

FDA Action
FDA will provide the report that the Committee requested.

Item 5 – Pediatric Cancer –The Committee notes that cancer remains the leading cause of disease-related death in children, that the incidence of childhood cancer is increasing, and that more effective and less toxic treatments are needed. The Committee encourages FDA to collaborate with industry and the pediatric cancer community to promote the development of new therapies.

FDA Action
FDA is committed to the development and approval of safe and effective new therapies for childhood cancer. To facilitate more active communication and collaboration between investigators, sponsors and regulators, FDA increased the frequency of annual meetings of the Pediatric Subcommittee of the Oncologic Drugs Advisory Committee to semi-annual. In addition, the meetings now focus on new cancer therapies to be used in earlier stages of pediatric development.

Sponsors of products which are potentially relevant to childhood cancers are invited to present data followed by in depth discussion with pediatric oncology experts resulting in advice to the Agency on the contents and submission of Written Requests to sponsors for pediatric studies. In addition, FDA pediatric oncology staff meet by monthly teleconference with NIH's Pediatric Oncology Working Group to solicit products of potential interest to the pediatric oncology investigator community. This information exchange is critical to the expeditious evaluation of potentially important new pediatric cancer drugs,

Item 6 – Tanning Devices – The March 2010 meeting of the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee recommended more accurate classification of tanning devices to save lives. FDA is encouraged to quickly promulgate an interim final rule to reclassify tanning devices.

FDA Action

The General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee convened in March, 2010, to receive testimony from more than 50 professional societies, industry representatives, melanoma survivors or family members of melanoma victims, and other interested parties on the public health issues surrounding tanning lamps. The expert panel reached a consensus that tanning beds and lamps should be up-classified from their current Class I medical device status to provide greater scrutiny of their safety and effectiveness. A majority of the panel also favored restricting tanning lamps to adult use and disclosing more information on the risks of tanning to consumers. FDA has reviewed the Advisory.

FDA has reviewed the Advisory Committee's recommendations to reclassify tanning lamps. FDASIA requires FDA to reclassify medical devices through a proposed and final administrative order process. FDA is in the process of developing the appropriate regulatory documents to address the risks associated with these medical devices.

Item 7 – Centers of Excellence – The Committee is aware of the important support provided to FDA's food and veterinary medicine programs and through its research and program relations with their centers of excellence. The Committee encourages FDA to maintain an appropriate funding level for both Food Safety Modernization Act related activities and the base work performed by these centers.

FDA Action

FDA will maintain an appropriate funding level for both Food Safety Modernization Act related activities and the base work performed by these centers.

Item 8 – Gluten-free Rulemaking – The Committee is aware of FDA's intention to issue a final rule by the end of 2012 to define gluten-free labeling of foods. The Committee encourages FDA to work with USDA to assist its agencies in adopting the definition of gluten-free set by the FDA final rule to provide uniform labeling requirements and best protect consumers with celiac disease and other conditions.

FDA Action

Issuance of the final gluten-free labeling rule continues to be a priority for FDA, and we anticipate its publication in the near future. FDA will continue to work with USDA on gluten-free labeling.

Item 9 – Antibacterial Resistance –To assist efforts intended to curb antibacterial resistance, the Committee directs the Secretaries of Agriculture and Health and Human Services to require agencies to: (1) seek public comment on collecting more detailed sales and distribution data for antibacterial drugs approved for use in food-producing animals, including estimates of the amount sold or distributed in specific animal species; (2) seek public comment on alternative methods for obtaining additional data and information about the extent of antibacterial drug use in food-producing animals; and (3) based on input received, work collaboratively to develop a strategy for implementing the

best approach. The Committee further directs FDA to ensure that the Agricultural Research Service continues to analyze, characterize, and report on data collected through NARMS.

FDA Action
FDA published an advance notice of proposed rulemaking (ANPRM) in the July 27, 2012 Federal Register, soliciting comments from the public on possible enhancements to the existing requirements related to the collection of antimicrobial drug sales and distribution data and on alternative methods for monitoring antimicrobial use in food-producing animals.

In response to several requests to allow interested persons additional time to submit comments, FDA extended the comment period from 60 to 120 days. The comment period closed on November 26, 2012, and FDA is currently performing an in-depth analysis of the submissions from a wide range of stakeholders as part of our ongoing efforts to enhance collaborative efforts to curb antimicrobial resistance. Further, FDA continues to collaborate with its NARMs partners at CDC and USDA – including the Agricultural Research Service – to analyze, characterize, and report on data collected through NARMs.

Item 10 – Mammography Quality Assurance –The Committee urges FDA to quickly follow up on the November 2011 meeting of the National Mammography Quality Assurance Advisory Committee by promptly reviewing the evidence supporting the inclusion of information related to an individual's breast density in the mammogram lay report and physician report.

FDA Action FDA has drafted regulation amendments currently under internal review that we believe will address the breast density reporting issue.

Item 11 – Food Safety Rulemaking – The Committee is aware the Administration missed the January 4, 2012, statutory deadline for publishing a notice of proposed rulemaking for fresh produce safety standards and final regulations on the content of the Foreign Supplier Verification Program for imported food. The Committee encourages the Administration to meet the statutory timelines for implementing P.L. 111-353 and expects FDA to follow a timeline for issuing rulemakings consistent with the sequence and logistics of establishing requirements for a preventive controls framework for domestic and imported foods. The Committee directs FDA to submit a report within 180 days of enactment of this Act that describes the justification for any proposed rule or final regulation being 60 days or more beyond the timeline. The Committee further directs FDA to continue to provide such report at the same time that the agency submits its annual budget justification to the Committee.

FDA Action
FDA will provide the report as requested by the Committee. On January 16, 2013, FDA published two proposed rulemakings, Preventive Controls for Human Food and Produce Safety Standards, mandated by FSMA. These foundational rulemakings, when implemented, will improve food safety and help modernize our food safety system.

Item 12 – Pathway to Global Product Safety – The Committee directs FDA to provide a report by June 1, 2013, on the implementation of the Pathway to Global Product Safety and Quality initiative.

FDA Action
FDA will provide the report as requested by the Committee.

Item 13 – Dietary Supplements – The Committee notes that FDA released draft guidance in July 2011 on New Dietary Ingredients (NDI) for Dietary Supplements. Though the Committee wants to ensure that dietary supplements are safe, it is concerned that the draft guidance is being utilized by FDA for enforcement activities against manufacturers despite the guidance only being in draft form, containing nonbinding recommendations, and for comment purposes only. The Committee urges FDA to withdraw the July 2011 NDI draft guidance and re-engage the dietary supplement community to develop a new guidance on what constitutes NDI.

FDA Action
FDA announced in July 2012 that we will be reissuing a revised NDI draft guidance for comment in order to add clarity where there was confusion regarding FDA's interpretation of the statutory authority in the NDI provision.

Item 14 – Food Contact Notification – The Committee directs FDA to maintain the fiscal year 2012 funding level for the Food Contact Notification program.

FDA Action
Subject to any changes to the FDA appropriation, after enactment, FDA will maintain the fiscal year 2012 funding level for the Food Contact Notification program.

Item 15 – Nutritional Ratings Systems – The Committee is concerned about the use of nutritional rating and front of package claims in the marketplace. To promote public health and facilitate consumer understanding, such information should be consistent with the Institute of Medicine's recommendations for front of package nutrition rating systems and symbols and the Dietary Guidelines for Americans and based on criteria that are public and readily available to consumers. Further, such systems and symbols should be evaluated by FDA to ensure their usefulness for American consumers, consistency with FDA nutrition programs, and compliance with relevant FDA food labeling requirements. The Committee directs FDA to provide a report regarding its plans to establish guidance for developing such systems and to provide the Committee a timetable for issuing such guidance.

FDA Action
FDA will provide the report as requested by the Committee.

Extensive analysis is required to assess the appropriateness and type of possible guidance to address front-of-package labeling concerns and ensure consistency with current regulations. To inform these decisions, FDA is working with the HHS Assistant Secretary for Planning and Evaluation on evaluating front-of-package labeling systems.

FDA is also monitoring the use of various front-of-package (FOP) labeling systems – including the system developed by the Grocery Manufacturers Association. FDA also issued a letter of enforcement discretion for the FOP labeling system developed by the Grocery Manufacturers Association and, as stated in the letter, intends to assess whether this system promotes public health and is useful to consumers. This letter may be found at: http://www.fda.gov/Food/LabelingNutrition/ucm302720.htm.

Senate Significant Items
Contained in Senate Report
Number 112-163
Date April 26, 2012

Item 16 – The Committee expects FDA to continue all projects, activities, laboratories, and programs as included in the fiscal year 2013 budget request, unless otherwise specified.

FDA Action
Subject to any changes to the FDA appropriation, after enactment, FDA will continue all projects, activities, laboratories, and programs as included in the fiscal year 2013 budget request, unless otherwise specified.

Item 17 – Antimicrobial Drugs – The Committee is encouraged by the finalization of FDA Guidance for Industry 209, which calls for the voluntary elimination of growth promoting uses of medically important antibiotics and increased veterinary oversight of these drugs. However, the Committee believes that FDA should continue to make progress to implement the recommendations outlined in the finalized Guidance for Industry 209. The Committee understands that the FDA has issued a companion draft guidance, Guidance for Industry 213, that provides further details on the strategy for implementing the changes recommended in guidance 209. Because of the importance of this issue to human and animal health, the Committee will continue to monitor FDA's efforts to finalize and implement the plan outlined in draft Guidance for Industry 213. The Commissioner is directed to provide a report regarding compliance with the final guidance and further details about how the FDA intends to meet its public health responsibilities. This report shall be due within 120 days of the completion issuance of the agency's final guidance for industry.

FDA Action
FDA will provide the report as requested by the Committee.

Item 18 – **Camelina –** The Committee recognizes the importance of developing markets for biofuel feedstock byproducts in building advanced biofuel supply chains. In particular, the Committee notes that multiple departments of government are currently engaged in advancing biofuel produced from Camelina. The FDA is directed to report to the Committee within 90 days after enactment of this Act on all previous petitions that have been approved at lower rations than requested, what regulatory barriers, if any, remain preventing a finding of `Generally Recognized as Safe' status for camelina, and how those barriers can best be overcome under current law and with the resources available to FDA.

FDA Action
FDA will provide the report as requested by the Committee.

Item 19 – **Artificial Pancreas** – The Committee is encouraged by the Food and Drug Administration's draft guidance for accelerating the development and availability of artificial pancreas technologies which have the potential to be an important tool for patients with type 1 diabetes to achieve better glycemic control, increasing their quality of life and overall health. The FDA's actions will allow these systems to be further developed, tested in outpatient pivotal trials, and eventually approved for people with type 1 diabetes. The Committee encourages the FDA to finalize the draft guidance and continue its interactions with researchers, clinicians, policymakers, and patient advocates to advance the development of artificial pancreas systems for people with type 1 diabetes.

FDA Action
On November 9, 2012, FDA finalized the draft guidance, “The Content of Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications for Artificial Pancreas Device Systems,” to help investigators and manufacturers develop and seek approval for artificial pancreas device systems to treat Type 1 diabetes.

FDA worked with many stakeholders to develop this final guidance and received approximately one hundred comments during the public comment period from physicians, professional societies, industry and patients. FDA took all public comments into account in the final version of the guidance.

The final guidance explains how regulatory burdens can be reduced, for example, by leveraging existing preclinical data from devices already on the market and by using existing safety and effectiveness information for individual device components that have already been approved or cleared by FDA.
FDA has continued its outreach efforts with researchers, clinicians, policymakers, and patient advocates to advance the development of artificial pancreas systems for people

with Type 1 diabetes by participating in conferences and meeting with interested parties throughout 2012. FDA is committed to ensuring that the devices that become available that utilize this technology provide a favorable benefit to risk profile for the patients that use them.

Item 20 – Budget Justification – The Committee directs FDA to submit the fiscal year 2013 budget request in a format that follows the same account structure as the fiscal year 2013 budget request unless otherwise approved by the Committee.

FDA Action
FDA will submit the fiscal year 2014 budget request in a format that follows the same account structure as the fiscal year 2013 budget request unless otherwise approved by the Committee.

Item 21 – Critical Path Initiative – The Committee expects FDA to continue its work on critical path, regulatory science and innovate opportunities, and to promote collaborations with other government agencies, academia, patient groups and other interested parties, including existing partnerships with academic institutions.

FDA Action
Subject to available funding, FDA will continue its support of public-private partnerships with academic institutions and other interested parties to advance critical path and regulatory science initiatives.

Item 22 – Dietary Supplements – The Committee is aware that U.S. consumers widely use plant-derived dietary supplements, and that FDA inspects manufacturers and distributors that are responsible for ensuring that such products are not adulterated or contaminated, and do not cause harm to the consumer. The Committee believes that methods and standards are needed to verify source plants and ingredients and to detect toxic contaminants. The Committee encourages FDA to develop guidance for industry on such methods and standards, which would enhance FDA's ability to inspect and assess industry practices for manufacturing botanical dietary supplements.

FDA Action
FDA's Center of Excellence at the University of Mississippi is currently conducting extensive work on methodologies for identification of botanicals. The Center's work in this area will inform FDA's next steps.

Item 23 – Drug Shortages –The Committee is concerned with the significant number of drug shortages occurring in the United States and the impact it is having on patient access to needed life-saving treatments. By Executive order, the President has instructed FDA to broaden its reporting of potential shortages and speed reviews of applications to begin or alter production of drugs in short supply. As part of this enhanced activity, the

Committee encourages FDA to increase its communication with medical practitioners through specialty-specific list serves and other means of targeted communications to provide information on potential shortages, the anticipated length of time of the shortage and options for obtaining therapies while they are in short supply.

FDA Action

FDA shares the Committee's concerns regarding drug shortages and the impact that these shortages have on patients. Preventing drug shortages is a top priority for FDA. The number of drug shortages has risen steadily since 2005 to a high of 251 shortages in 2011, and this is a very troubling situation that FDA takes very seriously. Once FDA becomes aware of a potential drug shortage, FDA works with pharmaceutical manufacturers to manage the shortage.

For products that are in shortage or may progress to a shortage, FDA expedites review of manufacturers' submissions. These submissions may support a marketing application for a new product under a New Drug Application (NDA) or an Abbreviated New Drug Application (ANDA), or may support manufacturing changes for existing products – for example, a supplemental application for a new manufacturing site.

In addition, FDA may:

- Help firms qualify additional manufacturing sites or raw material supplies, if those firms are interested in having additional manufacturing capacity
- Identify alternate manufacturers who can initiate or increase production
- Help manufacturers find and qualify new or additional sources of raw materials
- Advise and consult with sponsors on resolution of manufacturing issues
- Use enforcement discretion for the temporary importation of a non-U.S. product, after ensuring the drug does not pose undue risks for U.S. patients, and ensuring it is manufactured in a facility that meets FDA quality standards.

In order to provide healthcare providers with timely product information, including availability status and timeframes, alternate manufacturers, reasons for shortage, and firm contact information, FDA updates the FDA Drug Shortage website with product information on a daily basis.

Additional enhancements have been made to the Drug Shortage website as well, to improve navigation and to aid in easily finding information. The FDA Drug Shortage RSS Feed also provides drug shortage information and updates. In addition, FDA is considering additional mechanisms to further enhance communication of potential and actual shortages to medical practitioners.

Item 24 – **Ethanol –** The Committee directs the Food and Drug Administration to conduct periodic surveillance sampling of antibiotic use in ethanol production. The Food and Drug Administration should make public information about the results of its surveillance sampling.

FDA Action

The expansion of the fuel ethanol industry markedly increased the volume of distillers' products being produced and marketed as animal feed ingredients. In order for FDA to evaluate the impact of antibiotic use in ethanol production on animal feed it was necessary to analyze the distillers' products, which are the residual feed components of ethanol production, for antibiotic residues.

In 2007, FDA developed a method and published "Multiclass, multi-residue method for the detection of antibiotic residues in distillers grains by liquid chromatography and ion trap tandem mass spectrometry," in the Journal of Chromatography[1] and disseminated in Laboratory Information Bulletin 4438, "Analysis of Antibiotics in Distillers Grains Using Liquid Chromatography and Ion Trap Tandem Mass Spectrometry."[1]

In 2008 and in 2010, FDA conducted a survey of distiller's products for residues of antibiotics. The results of these surveys are available on the FDA website[2]. The 2010 results showed a significant decrease in the number of samples in which antibiotics were found. FDA will continue to monitor the presence of antibiotics in distillers' products through routine surveillance sampling or directed sampling and, when the results of sampling activities are complete, will continue to make such results available.

[1] http://www.fda.gov/downloads/AnimalVeterinary/Products/AnimalFoodFeeds/Contaminants/UCM151206.pdf
[2] http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/Contaminants/ucm300126.htm

Item 25 – **Honey** – The Committee recognizes that honey is produced in the United States, traded internationally and consumed as both a packaged food and as a food ingredient. However, there have been instances where manufacturers have been impermissibly marketing products as `honey' or `pure honey' that contained other ingredients. The Committee believes that guidance about the composition and labeling of honey is needed to protect consumers from misbranded and adulterated honey and honey-derived products that are currently entering the U.S. market. The Committee directs FDA to issue guidance to remind manufacturers of honey about the misbranding and adulteration provisions in law, about the proper labeling of honey, and other guidance that reinforces the FDA's existing labeling regulations.

FDA Action

FDA understands the concerns presented by the Committee and is currently working on drafting the guidance on honey. FDA will provide an update to the Committee when the draft guidance is ready to be published.

Item 26 – Nanotechnology – The Committee recognizes that FDA is developing the facilities and expertise to study nanotechnology at both its headquarters in Silver Spring, MD and within FDA's Jefferson Laboratory Campus, including the National Center for Toxicological Research. The Committee supports FDA in its mission to expand upon

current research in nanotechnology and supports the development of Nanotechnology Core Centers. The Nanotechnology Core Centers support the conduct of research to establish methods for use by agency scientists through providing access to equipment, expertise, and infrastructure. These activities include supporting nanotechnology toxicity studies, developing analytical tools to quantify nanomaterials in complex matrices, and developing procedures for characterizing nanomaterials in FDA-regulated products.

FDA Action
FDA investments will continue to enable us to address questions related to the safety, effectiveness, product quality, and regulatory status of products that contain nanomaterials or otherwise involve the use of nanotechnology; develop models for safety and efficacy assessment; and study the behavior of nanomaterials in biological systems and their effects on human health.

FDA will continue activities that meet the following FDA-wide priorities that are the basis of FDA's Nanotechnology Regulatory Science Research Program: (1) scientific staff development and professional training, (2) laboratory and product testing capacity, and (3) collaborative and interdisciplinary research to address product characterization and safety.

Item 27 – Information Technology – The Committee notes with concern that the Government Accountability Office [GAO] recently found that FDA does not have a comprehensive list of its information technology [IT] systems, and as a result, the agency cannot ensure that it is investing in the mix of projects that will best support its mission or that it is managing them appropriately. Given that FDA currently spends approximately ten percent of its overall funding on IT systems, the Committee insists that FDA address GAO's findings and determine the most efficient use of its IT resources. In addition, the Committee directs FDA to develop a comprehensive IT investment plan. Within 60 days of the enactment of this Act, the Committee directs FDA to provide a report on the agency's IT systems. The report shall include a complete inventory of systems, a description of each system's purpose, annual cost for each system and the source of funding, and status of each system including whether it is in the process of being upgraded.

FDA Action
FDA will provide the report as requested by the Committee.

Item 28 – Pediatric Devices – The Committee is pleased that the five FDA-funded Pediatric Device Consortia have assisted in advancing the development of 135 proposed pediatric medical devices, as well as promoted job growth in the healthcare sector, and as such, continues to support this critical effort. However, the Committee remains concerned that children's medical devices can lag 5 to 10 years behind those manufactured for adults and directs FDA to maintain funding at the current level.

FDA Action
Subject to any changes to the FDA appropriation, after enactment, FDA will maintain the fiscal year 2013 funding level for Pediatric Devices.

Item 29 – Seafood Advisory – The Committee is highly concerned that over a year has passed since USDA published its dietary guidelines and more than 6 months have passed since the publication of this Committee's fiscal year 2012 report directing FDA to commence reconsideration of its 2004 seafood advisory, and yet FDA has not published its draft revision of the advisory. Given data demonstrating that women of childbearing years, pregnant women, and mothers with young children are eating too little seafood for their health and the health of their babies, and the role the language of FDA's 2004 advisory may play in discouraging healthy consumption of seafood, the Committee expected a more urgent response by FDA. Therefore, the Committee directs FDA to issue final seafood advisory consistent with USDA's dietary guidelines by December 31, 2012.

FDA Action
FDA began reconsideration of its 2004 seafood advisory regarding the nutritional value of seafood consumption during pregnancy, in consultation with the Environmental Protection Agency (EPA), in 2011. FDA and EPA are working to issue updated seafood consumption advice. FDA will notify and provide this advice the committee in advance of its public release, as requested.

Item 30 – Tobacco – The Committee recognizes FDA has declared its intent to issue a proposed rule clarifying the agency's jurisdiction over tobacco products. The Committee strongly encourages the agency to issue this proposed rule and promulgate regulations as necessary. The Committee instructs the agency to consider, among other things, the issue of cigars with characterizing flavors, particularly as it applies to the marketing and sale of these products to children.

FDA Action
The Family Smoking Prevention and Tobacco Control Act provides FDA with the authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. The law also permits FDA to issue regulations deeming other “tobacco products,” such as e-cigarettes, certain dissolvable tobacco products, cigars, pipe tobacco, hookah, etc., to be subject to Chapter IX of the Food Drug & Cosmetic Act (FD&C Act). In the February 2012 edition of the Unified Agenda, FDA included an entry for a proposed rule that would deem products meeting the statutory definition of “tobacco product” to be subject to Chapter 9 of the FD&C Act and would clarify additional restrictions under the FD&C Act.

While the Agency cannot comment on the details related to a pending rulemaking, the Committee can be assured that FDA will continue to carefully consider the public health impact of the proposed rule, especially as it pertains to youth.

Item 31 – **Tanning Bed Labeling** –The Committee is aware of the FDA report to Congress as required by section 230 of Public Law 110-85, which determined that certain modifications to the labeling requirements for sunlamp products may communicate the risks of indoor tanning more effectively and stated that the agency was considering changes to the performance requirements of the sunlamp performance standard. The Committee encourages the agency to update the labeling and performance requirements for sunlamp products within 180 days of enactment of this act.

FDA Action

FDA has developed proposed amendments to the Performance Standard for Sunlamp Products in 21 CFR 1040.20. These amendments will improve safety, bring the requirements in line with current science and more closely harmonize them with the International Electrotechnical Commission Standard. The amendments include an improved warning label which strengthens the warnings to consumers about the risks of indoor tanning and makes them easier to read. This improved warning label was developed after the consumer focus group testing described in the required (by section 230 of Public Law 110-85) report to Congress.

These amendments are expected to publish during the first half of 2013 after review is completed.

Item 32 – Tissue Reference Group – To improve transparency, the committee urges the FDA to update FDA's procedures for the work of the Tissue Reference Group [TRG] to include specifying the format and content of submissions, projected timelines for review of inquiries, and procedures for sponsors to meet with FDA, and the process by which FDA communicates regularly with the sponsor regarding the submission. The committee further recommends that FDA conduct stakeholder meetings and use other means to make publicly available the scientific rationale for its recommendations regarding human cell, tissue, and cellular and tissue-based product jurisdiction and classification while protecting proprietary information. The committee directs the FDA to update on a biannual basis the TRG report summary the agency posts on its Web site, with the first update due within 90 days of enactment of the fiscal year 2013 appropriation.

FDA Action

FDA assembled a working group to update Standard Operating Procedure and Policy (SOPP) 8004 for the TRG. The working group meets to discuss how SOPP 8004 could be updated, including specifying the format and content requirements for submissions, timelines for issuing a response, and best practices for communicating with those submitting inquiries to the TRG. The TRG's SOPP Working Group is also currently considering what would constitute the most effective and efficient outreach activities. It is taking into consideration the method and manner of communication as well as how to provide specific, useful information without revealing trade secrets or other confidential information. The TRG plans to post updates on their website on a biannual basis, within 90 days of enactment of the fiscal year 2013 appropriation.

Significant Items
Contained in Senate/Labor/HHS Bill
Number 112-176
Date June 14, 2012

Item 33 – Drug Shortages –The Committee urges the Secretary, in consultation with FDA, to establish an interagency and intra-agency task force to address drug shortages. The task force should have stakeholder input, including an expert in how shortages affect pediatric patients. The study should examine whether other countries have experienced drug shortages, the extent and effect of the shortages, as well as any steps these countries are taking to mitigate or prevent such shortages.

FDA Action

FDA has expanded the drug shortage program to 11 full time staff who are dedicated to coordination efforts for prevention and mitigation of shortages. We have been able to prevent shortages and over 150 in 2012. We've prevented these shortages through working with firms on specific quality problems as well as through expedited reviews, asking other manufacturers to increase production, and also through temporary importation from overseas firms.

We have further expanded our program to include additional experts from throughout the Agency and we have a highly skilled team we can call upon for specific shortage issues including manufacturing experts, chemists, microbiologists, pharmacologists and clinicians including pediatric experts and other disciplines needed to help resolve and prevent specific issues. Furthermore, we have enhanced intra-Agency communications with the field staff (investigators) as well as our Office of Compliance regarding any issues that are potentially impacting supply at the manufacturers. In addition, we are in regular, if not daily, contact with various stakeholder groups, regarding products in shortage and drug shortage issues.

Drug shortages are not unique to the FDA or the US, but a global problem. FDA works closely with other regulatory authority (EMA, TGA, MHRA, HC) on existing drug shortage problems. During our discussions, under shared confidentiality agreements, crucial information regarding the availability of important drug products and potential alternate facilities is shared. Additionally, when a shortage is triggered by quality problems or manufacturing constraints to limited production capacity, FDA and other regulatory authorities exchange information regarding the quality issues identified or leading to the drug shortage, and communicate when necessary, with the company to explore options that will ensure the availability of drug products, while also ensuring that the drug is safe and effective.

State Fact Sheets

Fact Sheet – Alabama

FDA Presence

- 9 employees in Alabama
- Resident Posts in Birmingham, Mobile, and Montgomery
- Employees report to New Orleans District – in Nashville, TN
- Nashville, TN reports to Southeast Region in Atlanta, Georgia.

Industry Presence in State - 1,857 FDA-regulated establishments[46]

- Food establishments – includes cosmetics – 36 percent
- Medical Device and radiological establishments – 26 percent
- Human Drug establishments – 18 percent
- Animal drug and feed establishments – 14 percent
- Biological establishments – includes blood banks – 6 percent.

Industry Highlights

- 3 ports of entry – Mobile, Huntsville, Birmingham
- Mobile – exportation of grain products and importation of food and seafood products
- Seafood – primary food industry includes Gulf shrimp, crab, oysters from the coast and farm–raised catfish
- Agriculture – poultry, timber, cattle, cotton, soybeans, and peanuts
- Medical device presence
- Clinical research activity – medical university settings
- Biologics presence – regional blood testing facilities
- The Gulf Coast area – still recovering from Hurricanes Katrina & Rita in 2005
- Deepwater Horizon Oil Spill in 2010 severely affected the seafood industry.

Contracts, Partnerships & Special Programs

State Contracts

- Alabama Department of Public Health – food manufacturer sanitation inspections
- Alabama Department of Agriculture and Industries – BSE inspections.

State Partnerships

None

Special Programs

- Active Food Safety Task Force – AL Department of Public Health, AL Department of Agriculture, Auburn Cooperative Extension Service, AL Restaurant Association, AL Grocers' Association and AL Retail Foods Association.

[46] Some firms are in more than one category.

Fact Sheet – Alaska

FDA Presence

- 4 FDA employees in Alaska
- Resident Post – Anchorage
- Anchorage reports to: Seattle District in Bothell, WA
- Bothell, WA reports to Pacific Region in Oakland, CA

Industry Presence in State – 545 FDA–regulated establishments[47]

- Food establishments – includes cosmetics – 79 percent
- Medical device and Radiological establishments – 13 percent
- Human drug establishments – 3 percent
- *Biologic establishments, includes blood banks – 2 percent*
- Animal drug and feed establishments – 3 percent

Industry Highlights

- Alaska supplies most of America's salmon, crab, halibut, and herring
- Alaska is the number one producer of wild salmon in the world and has the only salmon industry certified as "sustainable "
- Alaska ranks as one of the top ten seafood producers worldwide. More than 6 million pounds of seafood are harvested off Alaska each year – 60% of all U.S. production
- The total value of Alaska seafood production has topped $2.5 billion annually for several years.
- Dutch Harbor and Kodiak consistently rank as two of the top three ports in the U.S. for tonnage of seafood brought in
- Alaska has over 33,000 miles of shoreline – more than the rest of the U. S. combined.

Contracts, Partnerships & Local Activities

State contracts

Alaska Department Environment and Conservation

- Conduct food safety inspections, conduct seafood HACCP inspections.

Alaska Department of Health

- Conduct inspections of mammography facilities.

State Partnerships

Alaska Department of Environmental Conservation

- Conduct inspections of the fish and fishery products processing industry for compliance with the Hazard Analysis and Critical Control Points (HACCP) regulations

[47] Some firms are in more than one category.

- Conduct mutual planning and sharing of reports for inspections, investigations, and analytical findings, related to food firms in the State of Alaska.

Fact Sheet – American Samoa

FDA Presence

- 9 FDA employees in Hawaii
- Resident Post – Honolulu
- Employees report to San Francisco District, Alameda, CA
- Alameda, CA reports to Pacific Region, Oakland, California

Industry Presence in State – 4 FDA–regulated establishments[48]

- Food establishments – includes cosmetics – 33 percent
- Animal drug and feed establishments – 33 percent
- Human drug establishments – 17 percent
- Biologic establishments – includes blood banks – 0 percent
- Medical device and Radiological establishments – 17 percent

Industry Highlights

- Tuna fishing and tuna processing plants are the backbone of the private sector, with canned tuna the primary export
- This is a traditional Polynesian economy – more than 90 percent of the land is communally owned

Fact Sheet – Arkansas

FDA Presence

- 373 FDA employees and 318 contractors in Arkansas
    - Dallas District Resident Post in Little Rock, Arkansas – Three investigators report to Dallas District Office.
    - Arkansas Regional Laboratory, Jefferson – Ninety-one employees report to Southwest Region, Dallas, Texas.
    - National Center for Toxicological Research (NCTR), Jefferson – 245 FTE+ 318 contractors.
    - 34 FDA headquarters employees that work onsite at NCTR

- Import entries are handled out of the Dallas Southwest Import District Office and through the Dallas District Staff located in Arkansas.

Industry Presence in State – 1,340 FDA–regulated establishments [49]

- Food establishments – includes cosmetics – 53 percent
- Animal drug and feed establishments –15 percent

[48] Some firms are in more than one category.
[49] Some firms are in more than one category.

- Medical device and Radiological establishments – 16 percent
- Human drug establishments – 13 percent
- Biologic establishments – includes blood banks – 3 percent

Industry Highlights

- Retail/Warehousing – Wal-Mart World headquarters in Bentonville, AR
- Eggs – Arkansas is a major egg production state
- Poultry – Arkansas is the home of several Tyson poultry production facilities
- Canning – Arkansas is the home of Allen Canning, Gerber and Bush food manufacturers
- Grains – Arkansas includes significant rice, wheat, corn, and soybean production
- Farming – Arkansas includes productive animal feed production and catfish farming
- Drug/Medical Devices – Baxter is located in Mountain Home, AR
- Southwest Import District – Approximately 647 line entries were received in Fiscal Year 2007. Primary products imported are alcoholic beverages, cosmetics, and animal drugs.

Contracts, Partnerships & Local Activities

State Contracts

- Arkansas Department of Health – conducts food sanitation inspections and inspections of mammography facilities
- Arkansas State Plant Board – conducts feed mill inspections; determines compliance with BSE Rule.

State Partnerships

- Arkansas Department of Health – shares oversight and authority of regulated dairy manufacturing facilities; agreement with the Jefferson Labs (NCTR) for emergency space; shares in an informal reciprocal agreement with ARL for FERN
- Local Activities, FERN – NCTR, an FDA research center, employs 225 government scientists and 318 contract support personnel who develop, modify or validate FDA regulatory standards
- Current work includes:
    - studies applying new technologies to provide data more easily extrapolated in humans
    - investigating the possibility of interspecies transfer of antimicrobial resistance mechanisms to humans
    - developing knowledge and techniques that will lead to the development of more effective drugs and more personalized medicine
    - defining methods of identifying subpopulations that are susceptible to particular chemical carcinogens and likely to experience adverse drug reactions or decreased drug efficacy
    - studying the interaction of light with cosmetic ingredients and tattoo pigments.

- Arkansas Department of Health Public Laboratory is a FERN Chemistry laboratory
- Dallas District Public Affairs Specialists – Respond to consumers and media inquiries and conduct consumer education outreach to diverse constituents, including a growing number of Hispanic workers employed by the poultry industry
- Southwest Import District Public Affairs Specialist – Focuses on Import issues, conducts education and outreach to the Import industry, State and other government officials, and supports border health issues

Fact Sheet – Arizona

FDA Presence

- 34 employees in Arizona (LOS-DO has 14 employees in Arizona)
- Resident Posts: Phoenix , Tucson
- Employees report to Los Angeles District, Irvine, CA
- Irvine, CA reports to Pacific Region, Oakland, CA
- Southwest Import District Resident Post – Nogales – 16 employees; San Luis, AZ – 3 employees who report to the Southwest Import District, Dallas, TX.

Industry Presence in State: 2,639 FDA–regulated establishments

- Food establishments – includes cosmetics – 39 percent
- Medical Device and Radiological establishments – 32 percent
- Human Drug establishments – 15 percent
- Biological establishments – includes blood banks – 5 percent
- Animal drug and feed establishments – 9 percent.

Industry Highlights

- 5 firms in Arizona that produce human biological products including 6 plasmaphoeresis centers and 4 American Red Cross facilities
- More than 10 manufacturers of vitamin and mineral Over-the-Counter products
- Southwest Import District received 532,568 line entries for fiscal year 2009. The primary products are: Fresh Produce, Frozen Shrimp, and Medical Devices.

Contracts and Partnerships:

State Contracts

- Arizona Radiation Regulatory Agency – inspections of mammography facilities
- Arizona Department of Agriculture – inspections of feed mills for medicated feeds and BSE.

State Partnerships

- Arizona Department of Agriculture – agree to establish working arrangements on mutual planning and share reports of inspection, investigations, and analytical findings on raw agricultural products

- Arizona Department of Health Services – coordinate retail food protection, including Hazard Analysis and Critical Control Points principles to control food safety hazards
- Southwest Import District Public Affairs Specialist – focuses on import issues, conducts education and outreach to the import industry, state and other government officials and supports border health issues.

Fact Sheet – California

FDA Presence

- 507 FDA employees in California –includes SWID & PRL–SW. 247 employees are in Southern California with the remaining in Northern California
- SAN–DO Resident Posts are in – Fresno, Sacramento, San Jose, and Stockton. South San Francisco Resident Post slated to open in 2011
- LOS–DO Resident Posts are in San Diego, San Pedro, Long Beach (CES) and Torrance (International Mail Facility), LAX, Ontario and Canoga Park
- Employees report to San Francisco District, Alameda, and Los Angeles District in Irvine which reports to the Pacific Region Office, Oakland
- Resident Posts – San Diego, San Pedro, LAX, Ontario and Canoga Park report to Los Angeles District, Irvine, which reports to Pacific Region, Oakland
- Pacific Region Laboratory Southwest, Irvine reports to Pacific Region, Oakland
- Southwest Import District Resident Posts – 40 employees – Otay Mesa, Calexico, San Diego Seaport/Airport, and Tecate report to Southwest Import District, Dallas, Texas which report to the Southwest Region, Dallas, Texas
- San Francisco District Laboratory, reports to San Francisco District, in turn reports to Pacific Region Office.

Industry Presence in State – 20,735 FDA–regulated establishments

- Food establishments – includes cosmetics – 42 percent
- Medical device and Radiological establishments – 37 percent
- Human drug establishments – 10 percent
- Animal drug and feed establishments – 8 percent
- Biologic establishments – includes blood banks – 3 percent

Industry Highlights

- California has the greatest number of medical device and biotechnology firms of any area in the US. They are concentrated in the San Francisco Bay Area, Orange County and San Diego areas
- California is a major producer of tree nuts and the only state that produces almonds
- California continues to lead the nation in the fresh vegetable market, accounting for 44 percent of the U.S. harvested area, 49 percent of the national production, and 50 percent of the total value, for the 24 selected crops estimated

- California receives an estimated 25 – 30 percent of all FDA regulated commodities imported into the US, and contains the largest harbor complex in the country. 1,100 ocean shipping containers, containing foodstuffs arrive each day in the Port of Los Angeles/Long Beach, increasing at approximately 20 percent annually. The district serves as the "Gateway to the Orient" for imports and exports and with the import operations along the U.S. and Mexico border, a significant "Gateway to Mexico " A total of 70 percent of all incoming cargo is believed to stay within the state boundaries
- Ports of entry along the California/Mexico border as well as the San Diego airport and seaport accounted for 2,036,846 line entries in Fiscal Year 2009
- Ports of entry along the California/Mexico border as well as the San Diego airport and seaport accounted for 3,162,823 line entries in Fiscal Year 2010.

Contracts & Partnerships

State Contracts

- California Department of Food & Agriculture (CDFA) – Conduct follow up investigations of reported tissue residues of food animals detected at the time of slaughter and conduct inspections of feed mills and BSE
- California Department of Public Health (CDPH) – Conduct inspections of food manufacturing facilities, mammography facilities and x–ray testing

State Partnerships

California Department of Food & Agriculture (CDFA)

- Coordinate efforts to prevent unsafe imported dairy products from entering commerce
- Coordinate inspections of medicated feed mills and residue investigations
- Coordinate regulatory activities involving pesticide residues on raw agricultural commodities.

California Department of Public Health (CDPH)

- Conduct inspections of seafood processing facilities
- Coordinate retail food protection efforts to promote HACCP principles for food safety
- Conduct inspections of all Acidified & Low Acid Canned Food processors
- Continue partnership with the laboratory in Los Angeles to co–locating employees and sharing equipment
- Establish partnership to co–locate employees in Sacramento
- Conduct inspections of new x–ray assemblies or re–assemblies
- Share inspectional and other information to ensure unified food safety programs
- Coordinate cooperative agreement to support the California Egg Quality Assurance Plan.

California Department of Pesticides Regulations

- Information exchange of positive Pesticides findings and firm follow up. California Department of Pesticides Enforcement Branch conducts sample collections and trace backs. Notifies FDA of violative samples for import targeting.

Other Partnerships in California

- Coordinate with American Council for Food Safety & Quality to maintain sanitation and compliance with regulations for dried fruit and tree nut products
- Information sharing with the University of California, Irvine, through an electronic communication system that transmits current health information regarding toxic substances throughout the California County Health Departments
- Southwest Import District Public Affairs Specialist – The primary focus is on Import issues. The SWID PAS conducts education and outreach to the Import industry, U.S. Customs Broker Associations, state and other government officials and supports border health issues.
- Collaborate with the Western Institute for Food Safety and Security (WIFSS) for outreach and education to food manufacturers, growers and distributors
- RRT State/Adopted Manufacturing Food Program Standards

Fact Sheet – Colorado

FDA Presence

- 138 FDA employees in Colorado in the Denver District Office which reports to the Southwest Region, Dallas, Texas
- Denver port of entry with one employee reports to Southwest Import District in Dallas, Texas
- Southwest Import District Reports to the Southwest Regional Office in Dallas Texas

Industry Presence in State – 2,802 FDA–regulated establishments

- Food establishments – includes cosmetics – 42 percent
- Medical device and Radiological establishments – 23 percent
- Human drug establishments – 15 percent
- Animal drug and feed establishments – 16 percent
- Biologic establishments – includes blood banks – 4 percent

Industry Highlights

- Colorado is a major cattle producer and also raises large numbers of hogs and sheep. Weld, Morgan, Larimer, and Boulder counties are the national center for the production of cattle fattened in feedlots rather than on the open range
- Colorado ranks high among the U.S. states in the amount of land under irrigation. Corn –maize, wheat, and hay are the major crops
- Colorado has a major food and food product industry

- The industrial and service sectors in Colorado have expanded greatly. The state's economy is diversified and is notable for its concentration of scientific research and high–technology industries
- Other Colorado industries include food processing, transportation equipment, machinery, chemical products, minerals, and tourism, particularly ski destinations such as Aspen and Vail
- Colorado also produces the largest amount of beer of any state
- Imports into Colorado – The Southwest Import District (SWID in Dallas) received 26,608 line entries for fiscal year 2010 through Colorado ports of entry. Primary products are medical devices, alcoholic beverages, cosmetics, and medical devices.

Contracts & Partnerships:

State Contracts

- Colorado Department of Public Health & Environment – conduct food sanitation inspections (231 total food inspections), and inspections of mammography facilities
- Colorado Department of Agriculture – Conduct inspections of feed mills for medicated feed and BSE Rule Compliance (85 total inspections)

State Partnerships

- Colorado Department of Public Health & Environment – Conduct inspections of artificial tanning facilities and conduct federal compliance testing of new assemblies or re–assemblies of x–ray equipment

Fact Sheet – Connecticut

FDA Presence

- 15 FDA employees in Connecticut (12 District, 1 Regional in Hartford, 1 Foreign Cadre in Hartford, and 1 Foreign Cadre in Bridgeport)
- Resident Posts: Hartford – 11 employees, and Bridgeport –4 employees; Report to New England District, Stoneham, Massachusetts, which reports to Northeast Region, Jamaica, New York.

Industry Presence in State – 1,686 FDA–regulated establishments

- Food establishments – includes cosmetics – 34 percent
- Medical Device and Radiological establishments – 43 percent
- Human drug establishments – 18 percent
- Animal drug and feed establishments – 2 percent
- Biologic establishments –includes blood banks – 3 percent

Industry Highlights

- Connecticut has 20 percent of the District's Official Establishment Inventory of regulated firms with an emphasis on food and medical devices

- Several major pharmaceutical manufacturers are located in the state
- Connecticut continues to hold dairy, poultry, tobacco, vegetables and fruit as its most important agricultural assets
- Several food and pharmaceutical companies comprise Connecticut's top 100 industries, , including United Natural Foods, Bozzuto's, Purdue Pharma, LP, and IMS Health, Inc.
- Included in Connecticut's top 25 imported products are cane,,beet sugar and coffee.

Contracts, Partnerships & Local Activities:

State Contracts

- Connecticut Department of Consumer Protection – conduct food sanitation inspections, conduct seafood and juice Hazard Analysis and Critical Control Point (HACCP) inspections, and participate in FDA's Manufactured Food Regulatory Program Standards
- Connecticut Department of Environmental Protection –Conduct inspections of mammography facilities.

Local Activities

- Connecticut has a Food Safety Task Force in which FDA is a participant.

Fact Sheet – Delaware

FDA Presence:

- 12 FDA employees in Delaware
- Resident Post: Wilmington
  Reports to: Philadelphia District, Philadelphia, Pennsylvania
  Reports to: Central Region, Chicago, Illinois

Industry Presence in State – 233 FDA-regulated establishments[50]

- Food establishments – includes cosmetics – 39 percent
- Medical device and radiological establishments – 31 percent
- Human drug establishments – 19 percent
- Animal drug and feed establishments – 6 percent
- Biologic establishments – includes blood banks – 5 percent

Industry Highlights:

- Active seafood industry

Contracts, Partnerships & Local Activities:

State contracts

- Delaware Department of Health – Conducts inspections of mammography facilities
- Conducts inspections of mammography facilities

[50] Some firms are in more than one category.

State Partnerships
Delaware Food Safety Council (DFSC)

- A partnership with the state and local governments, academia, industry, and USDA to address food safety issues.

Memorandum of Understanding
Delaware Department of Agriculture – Tissue Residue

Fact Sheet – District of Columbia

FDA Presence:

- 13 FDA employees in District of Columbia
- Resident Post: Falls Church Resident Post services Washington D.C
  Reports to: Baltimore District, Baltimore, Maryland
  Reports to: Central Region, Chicago, Illinois

Industry Presence in State – 309 FDA–regulated establishments

- Food establishments – includes cosmetics – 50 percent
- Medical device and Radiological establishments – 27 percent
- Human drug establishments – 13 percent
- Biologic establishments – includes blood banks – 9 percent
- Animal drug and feed establishments – 1 percent

Contracts & Partnerships:
State Partnerships
District of Columbia Department of Health, Health Care Regulation and Licensing Administration

- support DC Department of Health Food Safety Program in
- developing and coordinating resources
- provide training to augment the Retail Food Safety Program
- coordinate other activities, including inspection of food manufacturers and
- processors, food warehouses, and seafood facilities.

Fact Sheet – Florida

FDA Presence:

- 163 FDA employees in Florida (includes 6 students)
- Resident Posts: Boca Raton, Ft. Myers, Jacksonville, Miami (Domestic), Tallahassee, Tampa, Miami (Imports), Port Everglades (co–located with USCBP), Miami International Mail Facility
- Major Import Ports: Miami, Jacksonville, and Tampa
- Report to Florida District Office, Maitland, FL
- Maitland, FL reports to Southeast Region, Atlanta, GA

Industry Presence in Florida – 8,948 FDA–regulated establishments

- Food establishments – includes cosmetics – 41 percent
- Medical devices and Radiological establishments – 37 percent
- Human drug establishments – 15 percent
- Animal drug and feed establishments – 3 percent
- Biologics establishments – 4 percent

Industry Highlights:

- Miami – largest port in U.S. for importation of fresh seafood
- Miami – fifth largest port in U.S. for importation of FDA regulated commodities
- 359 class II & III medical device firms

Contracts, Partnerships & Local Activities:

State Contracts

- Florida Department of Agriculture & Consumer Services (FDACS), Division of Food Safety contracted to perform food safety and seafood HACCP inspections
- FDACS, Division of Agricultural Environmental Services contracted to perform BSE inspections
- Florida Department of Health contracted to conduct mammography and x–ray inspections.

Cooperative Agreement

- FDACS, Division of Agricultural Environmental Services – cooperative agreement with FDA for BSE surveillance activities.

Partnership

- FDACS, Bureau of Chemical Residue Laboratories shares volatile pesticide residue results from imported and domestic produce with FLA–DO.

Collaborative Activities

- FLA-DO works with FDACS, Divisions of Food Safety, and Agricultural Environmental Services, and Office of Agricultural Emergency Preparedness, Florida Department of Health and Florida Department of Business & Professional Regulation to develop a rapid response team.

Fact Sheet – Georgia

FDA Presence:

- 247 FDA employees in Georgia
- Resident Posts in Georgia: Middle Georgia, Savannah, and Tifton
  Report to: Atlanta District, Atlanta, who
  Reports to: Southeast Region, Atlanta
- Southeast Regional Laboratory, Atlanta
  Reports to: Southeast Region, Atlanta
- HQ employees in GA: Facilities – 2, Financial Mgmt. Br.– 3, OAGS – 2, OC – 1, LMR – 1, DHRD –1, CFSAN – 1, DFS – 1, DFI – 1, OSITS – 5.

Industry Presence in State – 3,299 FDA-regulated establishments

- Food establishments – includes cosmetics – 45 percent
- Medical Device and Radiological establishments – 29 percent
- Human Drug establishments – 12 percent
- Animal Drug and Feed establishments – 10 percent
- Biologic establishments – includes blood banks – 4 percent

Industry Highlights:

- American Red Cross Regional Blood Bank
- Life Share Corp. HQ (formerly Serologicals) – major plasmapheresis center
- Cryolife – largest/major tissue bank processor
- Atlanta Hartsfield-Jackson International Airport land port – 85,510 import entries per annum – condoms, gloves, seafood, produce, medical devices
- Savannah seaport –118,046 import entries per annum – canned foods, medical devices, bulk grains, agricultural products, and juices
- Brunswick seaport – less than 80 entries per annum – 90% seafood.

Contracts, Partnerships & Local Activities:

State Contracts

Georgia Department of Agriculture

- inspects for food sanitation, feed mills, and BSE
- Inspects egg facilities.

Georgia Department of Natural Resources

- inspects mammography facilities.

Other Partnerships

- training activities to promote health and scientific education with Morris Brown College
- educational activities to promote health and dispense information on disease prevention with Spellman College
- development of problem solving models associated with complex scientific and public health challenges in minority communities with Morehouse School of Medicine.

Local Activities

- Assist state laboratories with analytical issues
- FDA ACNA Lab (National nutrition analysis/labeling service lab)
- Microbiology and Chemistry labs for foods, drugs, and cosmetics
- Georgia Food Safety & Defense Task Force
- Interagency Pest Risk Committee

Fact Sheet – Guam

FDA Presence:

- 9 FDA employees in Hawaii
- Resident Post: Honolulu
- Honolulu reports to: San Francisco District, Alameda, CA
- San Francisco reports to Pacific Region, Oakland, CA

Industry Presence in State – 35 FDA–regulated establishments

- Food establishments – includes cosmetics – 63 percent
- Medical device and radiological establishments – 23 percent
- Human drug establishments – 8 percent
- Biologic establishments – includes blood banks – 6 percent

Industry Highlights:

- More than half of the few FDA-regulated firms in Guam are related to the food industry, with the remaining spread fairly evenly among biologics, drugs, and device industries
- Guam exports copra, fish, and handmade goods
- Maize, cassava, bananas, and coconuts are grown for domestic consumption
- The island is also an important re-export center for distribution of goods throughout the Pacific, particularly to Micronesia.

Fact Sheet – Hawaii

FDA Presence:

- 9 FDA employees in Hawaii
- Resident Post: Honolulu
- Reports to: San Francisco District, Alameda, California, who
- Reports to: Pacific Region, Oakland, California

Industry Presence in State – 646 FDA–regulated establishments

- Food establishments – includes cosmetics – 59 percent
- Medical device and radiological establishments – 28 percent
- Human drug establishments – 7 percent
- Biologic establishments – includes blood banks – 4 percent
- Animal drug and feed establishments – 2 percent

Industry Highlights:

- Staff an International Mail Facility in conjunction with DHS/CBP (Customs and Border Protection) to detain counter drugs via international mail

- Seafood, domestic and imports, is the largest industry on the Islands
- Importation of goods to and through Hawaii to the mainland accounts for 1/3 of FDA resources covering the review, inspection and sampling of products primarily from Asia.

Contracts, Partnerships & Local Activities:

State Contracts

Hawaii Department of Health

- Conduct inspections of mammography facilities
- Conduct diagnostic x-ray field tests.

State Partnerships

Hawaii Department of Health

- Conduct inspections of new x-ray assemblies or re-assemblies
- Support for a Food Safety Task Force for food safety.

Hawaii Department of Agriculture & Department of Health

- Support the Egg Quality Assurance Plan, an integrated voluntary food safety program designed to ensure quality and safety of eggs (with USDA, University of Hawaii and industry).

Local Activities

Ongoing public affairs cooperation with the

- Hawaii Food Manufacturers Association,
- University of Hawaii,
- Hawaii Cooperative Extension Service,
- Hawaii Dietetic Association,
- Hawaii Section/Institute of Food Technologists, and
- Hawaii Department of Health.

Fact Sheet – Idaho

FDA Presence:

- 8 FDA employees in Idaho
- Resident Post: Boise, Eastport
  Report to: Seattle District, Bothell, Washington
  Reports to: Pacific Region, Oakland, California

Industry Presence in State – 943 FDA–regulated establishments

- Food establishments – includes cosmetics – 59 percent
- Animal drug and feed establishments – 12 percent
- Medical device and radiological establishments – 15 percent
- Human drug establishments – 12 percent
- Biologic establishments – includes blood banks – 2 percent

Industry Highlights:

- Idaho is number one in the nation in the production of potatoes, trout and winter peas. Idaho produces 30% of U.S. potatoes, 50% of processed potatoes and 76 % of food size trout. The state ranks in the top 10 in 22 other agricultural products.
- Out of 144 commodities, Idaho is in the top 10 in more than 30
- Food processing is the second largest industry, next to high tech. Idaho's high–tech industry is one of the state's largest employers
- The dairy industry is the largest single agricultural industry

Contracts, Partnerships & Local Activities

State Contracts

- Conducts food sanitation inspections

State Partnerships

- Idaho Department of Health and Welfare
- Establish working arrangements for food safety and sanitation inspections of food firms
- Inspect new x-ray assemblies or re-assemblies

Idaho Department of Agriculture

- Participation with the Idaho Bureau of Homeland Security Agro-Terrorism Group
- Regular interaction with Idaho Tech help to provide training to regional food processing companies

Fact Sheet – Illinois

FDA Presence:

- 124 FDA employees
- ORA Central Region Headquarters – 24 FDA employees
- Chicago District Office – 100 FDA employees
  Resident Posts: Mt. Vernon, Gurnee, Peoria, Hinsdale, Springfield, and O'Hare
  Report to: Chicago District, Chicago, Illinois
  Reports to: Central Region, Chicago, Illinois

Industry Presence in State – 5,792 FDA-regulated establishments

- Food establishments – includes cosmetics – 43 percent
- Medical device and Radiological establishments – 36 percent
- Human drug establishments – 10 percent
- Animal drug and feed establishments – 8 percent
- Biologic establishments – includes blood banks – 3 percent

Imports:

- Imports – 500,000 lines processed per year
- Primary imports are alcoholic beverages (finished), bakery products, vegetables and fruit
- Receives product from 129 countries

Industry Highlights:

- Food processing is the state's number one manufacturing activity. State is the number one pumpkin and horseradish producer in the U.S. as well as one of the top soybean and corn producing states
- Number of high risk food firms is 462
- Number of class I device firms is 390 and the number of class II device firms is 281
- Archer Daniels Midland headquarters– $70B in revenue. ADM is the world's largest corn processor and the biggest processor of oil seeds – soybeans, cottonseed, sunflower seeds, and flaxseed in the U.S.
- World's largest wet corn mill owned by ADM
- Kraft Foods headquarters – $48B in revenue – Second largest food company in the world. Has 11 brands with revenues exceeding $1 billion, including: Kraft, Jacobs, LU, Maxwell House, Cadbury, Trident, Milk, Nabisco and its Oreo brand, Philadelphia, and Oscar Mayer
- Abbott Laboratories – $30B in pharmaceutical revenue
- Baxter International and Medline Industries, Inc. – both are Fortune 250, $10B medical device firms
- World class medical research universities include the University of Illinois, Northwestern University, University of Chicago, and Rush University Medical School, National Center for Food Safety and Technology
- Headquarters of PepsiCo Americas, Sara Lee, Walgreens McDonalds
- Largest U.S. source of pumpkins and pumpkin canning
- Major distribution hub for country – 300 of Fortune 500 companies operate major regional or national distribution centers in Illinois. There are 3,000 public warehousing facilities and 6,000 trucking companies.

Contracts, Partnerships, and Local Activities:

State Contracts

Illinois Department of Agriculture

- Feed mill inspections: 100 Bovine Spongiform Encephalopathy (BSE) and 13 Good Manufacturing Practices (GMP)

Illinois Department of Public Health

- Food safety inspections: 390 food inspections per year, 20 seafood inspections, and 5 Low acid canned food (LACF) inspections

Illinois Department of Revenue, Liquor Control Commission

- Tobacco Compliance and Enforcement: Conduct inspections of retail establishments to enforce the Youth Access and Advertising Regulations that took effect on June 22, 2010

State Cooperative Agreements (Grants)

Illinois Department of Agriculture

- Bovine Spongiform Encephalopathy (BSE): $1.2 million dollar cooperative agreement over five years – In previous two years over 1,000 cattle feed samples were analyzed

Illinois Dept. of Public Health Laboratory, for Microbiology

- Microbiology Program: Food Emergency Response Network (FERN) laboratory to provide additional capacity for analyzing food samples in the event of food borne disease outbreaks or other large scale food emergency events

Partnerships

Illinois Public Health Association

- Support annual Illinois Food Safety Symposium, HIV/STD Conference, Emergency Meeting and more

Great Lakes Regulatory Science and cGMP Conference

- This is a co-sponsorship agreement to promote understanding between FDA, industry, and academia on pharmaceutical manufacturing issues

Institute for Food Safety and Health

- This national partnership exists between the Illinois Institute of Technology, FDA, and the food industry to strengthen understanding of food safety science

Fact Sheet – Indiana

FDA Presence:

- 23 FDA employees in Indiana
- Resident Post: Indianapolis, Evansville, and South Bend
  Reports to: Detroit District Office, Detroit, Michigan
  Reports to: Central Region, Chicago, Illinois

Industry Presence in State – 2,786 FDA-regulated establishments

- Food establishments – includes cosmetics – 45 percent
- Medical Device and Radiological establishments – 26 percent
- Animal drug and feed establishments – 13 percent
- Human Drug establishments (includes Medical Gas) – 12 percent
- Biological establishments – includes blood banks – 5 percent
- Bioresearch Monitoring establishments – 4 percent

Industry Highlights*:*

- Major drug manufacturers include Eli Lilly, Bristol Myers Squibb, Pfizer, Baxter, Cook, and Schwarz.
- Home to three of the world's largest orthopedic implant makers (Zimmer, Biomet, and DePuy), and major diagnostics manufacturer, Roche Diagnostics. Other large device firms such as Cook Inc., and Hill-Rom.
- Very active Medical Device Industry Association known as the Indiana Medical Device Manufacturers Council (IMDMC). Played a major role in implementation of FDA Modernization Act (FDAMA) and medical device inspection initiatives
- Infant formula manufacturer, Mead Johnson Nutrition
- Federal Express Hub in Indianapolis

Contracts & Partnerships*:*

State Contracts

Indiana Board of Health:

- Conduct inspections of mammography facilities
- Egg Rule Contract (New FY11)

Purdue University (Indiana Office of State Chemists)

- Conduct medicated feed mill and BSE inspections.

State Partnerships

Indiana Department of Health:

- Coordinate inspection plan to increase consumer safety by coordinating inspectional information of non-retail food establishments.

Indiana State Board of Animal Health:

- Share information on tissue residues in food producing animals

Fact Sheet – Iowa

FDA Presence:

- Ten FDA employees in Iowa
- Resident Posts: Davenport (2), and Des Moines (8)
  Report to: Kansas City District, Lenexa, Kansas
  Reports to: Southwest Region, Dallas, Texas

Industry Presence in State – 2,210 FDA-regulated establishments

- Food establishments – includes cosmetics – 50 percent
- Animal drug and feed establishments – 28 percent
- Medical device and radiological establishments – 13 percent
- Human drug establishments – 7 percent
- Biologic establishments – includes blood banks – 2 percent

The Southwest Import District is responsible for imported products into Iowa. The primary imported products are alcoholic beverages, medical devices, and drugs.

Industry Highlights:

- Diverse, with all major FDA program areas represented
- Iowa ranks number one in the nation in revenue from the production and marketing of corn, soybeans and hogs
- Food processing remains Iowa's leading manufacturing industry
- Iowa has a heavy concentration of In-vitro diagnostic establishments:
- In-vitro diagnostic establishments: Iowa has a heavy concentration of these
- Bioresearch: One of the few bioequivalency testing facilities in the country
- State reports 1800 biotech firms and rank 1st in number of acres producing biotech corn and soybeans

Contracts, Partnerships & Local Activities:

State Contracts

Iowa Department of Agriculture and Land Stewardship

- Conduct inspections of medicated feed mills to ensure safety and BSE control
- Conduct targeted egg inspections in response to major recall in 2011

Iowa Department of Inspections and Appeals

- Conduct food safety inspections

State Partnerships

Iowa Department of Agriculture and Land Stewardship

- Coordinate oversight of regulated dairy manufacturing facilities
- Awarded partnership to upgrade automation hardware to support cooperation with FDA at national and District levels

Local Activities

- Iowa Food Safety Task Force – Established under FDA-funded grant
- Iowa is one of 8 states awarded FDA funding under a cooperative agreement to enhance their animal safety and BSE prevention programs
- KAN-DO coordinated with the State of Iowa in response to major flooding along the Missouri river in 2011. Disaster continues to have major impact on crops and agricultural land in Iowa and Missouri
- Kansas City District houses FDA's Total Diet Research and Pesticide Center Laboratory

Fact Sheet – Kansas

FDA Presence:

- 133 FDA employees in Kansas
- Resident Posts: Wichita (5)
  Reports to: Kansas City District, Lenexa, Kansas, who
  Report to: Southwest Region, Dallas, Texas

- Regional Staff: Lenexa (3)
- Headquarters Staff: DFO/OITSS Staff: Lenexa (4); & DFI Staff: Lenexa (1); DFSR Staff: Manhattan (1); OSS (1)

Industry Presence in State – 2,027 FDA-regulated establishments

- Food establishments – includes cosmetics – 52 percent
- Animal drug and feed establishments – 24 percent
- Medical device and radiological establishments – 15 percent
- Human drug establishments – 7 percent
- Biologic establishments – includes blood banks – 2 percent

Industry Highlights:

- Agriculture-based economy
- Top producer of wheat, sorghum, corn, and sunflowers
- Produced 6.6 million head of cattle in the year 2000
- Significant animal feed industry
- The largest concentration of animal health industry in the world between Manhattan (KS) and Columbia (MO)
- The Southwest Import District is responsible for imported products in Kansas. The primary products imported are grain, seafood, animal drugs/devices, fresh vegetables, and cosmetics.

Contracts and Partnerships:

State contracts

Kansas Department of Agriculture (KDA)

- Conduct inspections of medicated animal feed mills to ensure safety and BSE control
- Conduct food safety inspections

Kansas Department of Health and the Environment

- Conduct mammography facility inspections

State Partnerships

Kansas Department of Agriculture

- Share responsibility for regulating dairy manufacturing facilities.

Local Activities

- KAN-DO is cooperating with state and local regulatory officials in Kansas to develop a statewide “food and agriculture emergency plan”
- Kansas is one of 8 states awarded FDA funding under a cooperative agreement to enhance their animal safety and BSE prevention programs
- Kansas City District houses FDA’s Total Diet Research and Pesticide Center Laboratory

Fact Sheet – Kentucky

FDA Presence:

- 13 FDA employees in Kentucky
- Resident Post: Louisville
  Reports to: Cincinnati District, Cincinnati, Ohio
  Reports to: Central Region, Chicago, Illinois

Industry Presence in State – 1,913 FDA-regulated establishments

- Food establishments – includes cosmetics – 53 percent
- Medical device and Radiological establishments – 22 percent
- Human drug establishments – 12 percent
- Biologic establishments – includes blood banks – 4 percent
- Animal drug and feed establishments – 9 percent

Industry Highlights:

Contracts, Partnerships & Local Activities:

State Contracts

Kentucky Department of Public Health

- Conduct inspections of mammography facilities
- Conduct food safety inspections including Seafood HACCP
- Biannual meetings with Food Safety Branch

University of Kentucky

- Conduct inspections of medicated feed mills and BSE
- Yearly meeting with UK Regulatory Services – CVM/Feed issues.

State Partnerships

Kentucky Cabinet for Health Services of Commonwealth of Kentucky

- Coordinate testing of new and reassembled x-ray equipment
- Coordinate testing of new and reassembled x-ray equipment
- FDA provided funding so KY employees could attend FDA training courses
- CIN-DO developed a Tissue Residue Outreach Program to discuss illegal drug residues with farmers throughout the state
- Participated in Food Inspections including environmental sampling.

Local Activities

- CIN-DO attends Kentucky Food Safety Task Force meetings composed of State, Federal, Academic, and Industry Representatives with an interest in food safety and security
- CIN-DO holds an annual partnership meeting with KY Feed and KY Food Safety.

Fact Sheet – Louisiana

FDA Presence:

- 18 FDA employees in Louisiana
- Resident Posts in Louisiana: Baton Rouge, Covington, Lafayette, Mandeville, Metairie, and Shreveport
- Report to: New Orleans District (currently located in Nashville, TN), who
- Reports to: Southeast Region: Atlanta, Georgia

Industry Presence in State – 2,530 FDA-regulated establishments

- Food establishments – includes cosmetics – 58 percent
- Medical device and Radiological establishments – 19 percent
- Human drug establishments – 13 percent
- Biologic establishments – includes blood banks – 5 percent
- Animal drug and feed establishments – 5 percent

Industry Highlights:

- Seafood –a primary industry supplying large volumes of shrimp, crawfish, crabs, oysters and fish. Fish include native wild and farm-raised, marine and fresh water species
- Imports – New Orleans is a major port, with green coffee the leading commodity
- Agriculture – major portions of Louisiana are supplying agricultural products, such as rice, soybeans, corn, sugar cane, poultry and cattle. Timber is the largest and most valuable agricultural product in Louisiana.
- Exports – Using the Mississippi River for transportation, the mid-continent of the United States markets its grain products to the world through port facilities located along the river in the vicinity of New Orleans.
- The Gulf Coast Area was affected by Hurricanes Katrina & Rita in 2005 and Hurricane Gustave in 2008. The industry is still recovering and will continue to be for a number of years.
- The Deepwater Horizon oil spill in 2010 has significantly affected the Gulf Coast seafood industry.
- A 2010 oil leak in an Assumption Parish sugarcane field caused substantial damage to crops in that area.

Contracts & Partnerships:

State contracts

Department of Health and Hospitals

- Conduct inspections of food for sanitation and seafood for Hazard Analysis and Critical Control Points (HACCP) requirements.

Department of Agriculture and Forestry

- Conduct follow-up investigations of violative tissue residues in food animals at the time of slaughter.

State Partnerships

Department of Health and Hospitals

- Coordinate public health emergencies in mutual areas of responsibility
- Share oversight and authority of regulated dairy manufacturing facilities

Department of Agriculture & Forestry

- Maintain a program for monitoring pesticide residues in raw agricultural commodities.

Special Programs

- LA Food Safety Network, established in 2007, which consists of: LA Department of Health & Hospitals; LA Department of Agriculture & Forestry; U.S. Department of Agriculture; LSU Extension Service; LA Restaurant Association and LA Grocers' Association

Fact Sheet – Maine

FDA Presence:

- 18 FDA employees in Maine, including one Foreign Cadre (Augusta)
- Resident Post: Augusta (10 employees) and
- Border Stations: Houlton (4 employees) and Calais (4 employees)
  Report to: New England District, Stoneham, Massachusetts, who
  Reports to: Northeast Region, Jamaica, New York

Industry Presence in State – 985 FDA-regulated establishments

- Food establishments – includes cosmetics – 69 percent
- Medical Device and Radiological establishments – 16 percent
- Human drug establishments – 9 percent
- Animal drug and feed establishments – 4 percent
- Biologic establishments – includes blood banks – 2 percent

Industry Highlights:

- Maine's inventory of firms makes up 11% of the District's Official Establishment Inventory of FDA-regulated firms, with the majority of those firms involved in the production and distribution of foods, and more than half of those firms involving seafood/shellfish products.
- Maine's agricultural outputs are seafood (notably lobsters), poultry and eggs, dairy products, cattle, blueberries, apples, and maple sugar. Aroostook County is known for its potato crops. Western Maine aquifers and springs are a major source of bottled water (Poland Spring water is the Northeast's preferred brand).
- Included in the State of Maine's top 25 imported products are food items, such as potatoes and salmon which arrive at various ports of entry. Most imported goods enter the State from Canada.

State Contracts & Partnerships:

State Contracts

Maine Department of Agriculture

- Conduct food sanitation inspections
- Conduct seafood and juice HACCP (Hazard Analysis and Critical Control Point) inspections

Maine Department of Human Services

- Conduct inspections of mammography facilities
- Participates in FDA's Manufactured Food Regulatory Program Standards.

Local Activities

- Maine has the Food Safety Group that meets to discuss food safety issues and allows us to foster contacts in the event of a food emergency. The group is made up of ME CDC, Agriculture, Health Inspection Program, Education, U Maine Cooperative extension, Marine Resources and FDA.
- Maine is also represented on the Board of Directors of the Northeast Food and Drug Officials Association (NEFDOA) by Hal Prince at the Maine Dept. of Agriculture, Food & Rural Resources and Lisa Brown at the DHHS Health Inspection Program. An annual training conference in Mystic Connecticut was held in May 2011.
- Hal Prince also attended the AFDO Annual Education Conference in Plano TX in June 2011.
- Maine Department of Agriculture and the DHHS Health Inspection Program are jointly hosting the FDA Northeast Region Annual Food Protection Seminar in Portland Maine in August 2011.

Fact Sheet – Maryland

FDA Presence:

- 66 FDA employees in Maryland
- Resident Posts: Dundalk Marine Terminal (imports)
  Reports to: Baltimore District, Baltimore, Maryland
  Reports to: Central Region, Chicago, Illinois

Industry Presence in State – 2,837 FDA-regulated establishments

- Food establishments – includes cosmetics – 46 percent
- Medical device and Radiological establishments – 31 percent
- Human drug establishments – 11 percent
- Biologic establishments – includes blood banks – 5 percent
- Animal drug and feed establishments – 7 percent

Industry Highlights:
The industry in the state is very diverse and representative of the FDA national inventory, including large, medium and small firms active in all FDA regulated industries:

- Federal Food Service facilities
- Seafood
- Spices
- Bioresearch monitoring facilities (clinical investigators)
- Biotech facilities
- Imported products through the Port of Baltimore and BWI Airport

Contracts & Partnerships:
State Contracts
Maryland Department of Health and Mental Health

- Food/Seafood: Contract includes 180 inspections of food/seafood manufacturers, repackers, distributors, and warehouses; and collection of 21 samples.

Maryland Department of Agriculture

- Tissue Residue: Contract includes 5 inspections in follow-up to USDA findings of drug residues in excess of established tolerances in animals sold for human consumption.
- Bovine Spongiform Encephalopathy (BSE): Contract includes 50 inspections of feed manufacturers, retail operations, haulers and collection of 150 feed samples.

Fact Sheet – Massachusetts

FDA Presence:

- 173 FDA employees in Massachusetts including the Regional Food & Drug Director, District Director, Compliance Branch, Investigations Branch, Management Program and Support Branch, State Programs Branch, Winchester Engineering and Analytical Center (WEAC), Regional Emergency Response Coordinator, QMS, and Public Affairs
- Resident Post: Worcester (5 employees) and
- Border Station: Boston (12 employees)
  Report to: New England District, Stoneham, MA, District employees (92)
  Reports to: Northeast Region, Jamaica, NY
- Regional Food & Drug Director, WEAC (50 employees), State Programs Branch (5), Regional Quality System Manager, and the Regional Emergency Response Coordinator who
  Report to: Northeast Region, Jamaica, NY
- HQ employees: DCIQA (1), DIO (2), DFSR (1), OAGS (1), QMS (1) (District)

Industry Presence in State – 3,990 FDA-regulated establishments

- Food establishments – includes cosmetics – 45 percent
- Medical Device and Radiological establishments – 35 percent
- Human drug establishments – 13 percent

- Animal drug and feed establishments – 2 percent
- Biologic establishments – includes blood banks – 5 percent

Industry Highlights:

- Houses almost one–half of the regulated industry in New England with special emphases in biotechnology, medical devices, and foods. Serves as corporate headquarters for many of these firms
- In addition, as a coastal state, Massachusetts has a large inventory of seafood establishments. Massachusetts is one of the leading commercial fishing states. New Bedford accounts for about half the scallops produced in the nation. This industry delivers a broad range of product including cod, flounder, haddock, lobster, ocean perch, whiting, clams, crabs, hake, herring, pollock, squid, swordfish and tuna.
- Massachusetts' top five agricultural products are greenhouse and nursery products, cranberries, dairy products, sweet corn, and apples.
- The state is one of the world's important medical research centers and private universities and colleges are major employers.
- Included in the Commonwealth of Massachusetts' top 25 imported products are medical devices, food products and seafood.
- The WEAC laboratories provide specialized analytical services in engineering, medical device and radionuclide analysis. In this regard, the WEAC facility is FDA's only major field laboratory installation to provide service in these areas. WEAC is the primary field laboratory upon which CDRH relies for its analytical services. All engineering analysis for the GWQAP analytical program is performed at WEAC. In addition to the specialized analytical procedures for radionuclides in foods and radiopharmaceuticals, WEAC performs chemical and microbiological testing.

State Contracts and Partnerships:

State Contracts

Massachusetts Department of Public Health

- Conduct inspections of mammography facilities
- Conduct food sanitation inspections
- Conduct seafood HACCP (Hazard Analysis and Critical Control Point) inspections
- Participate in FDA's Manufactured Food Regulatory Program Standards

Local Activities

- FDA is a participant in Massachusetts Partnership for Food Safety and the Massachusetts Coalition for Food Safety and Defense activities.
- Massachusetts has applied to participate in the Food Protection Task Force Conference.

- The Massachusetts Bureau of Environmental Health (BEH) accepted an FDA Food Protection Rapid Response Team (RRT) and Program Improvement Prototype Project Grant. Through the cooperative agreement the Bureau (BEH) will enhance the capacity of its Food Protection Program (FPP) through continuous program assessment and staff development and training. MDPH proposes to work closely with FDA over the course of three years to enhance food emergency response capacity by improving existing regulatory programs for manufacturing facilities. The FDA Food Protection Plan will be incorporated into the FPP enhancements in order to implement food safety prevention, intervention and response into all steps of the food supply chain.
- Commonwealth of Massachusetts, in conjunction with FDA's New England District Office, hosted the National Center for Biomedical Research and Training (NCBRT) course: A Coordinated Response to Food Emergencies: Practice and Execution. This was held on January 24-25, 2011.

Fact Sheet – Michigan

FDA Presence:

- 113 FDA employees in Michigan
- Resident Posts: Grand Rapids, Kalamazoo, Detroit Ambassador Bridge, Port Huron and Sault Saint Marie
  Report to: Detroit District Office, Detroit, MI
  Reports to: Central Region Office, Chicago, IL

Industry Presence in State – 3,784 FDA–regulated establishments

- Food establishments – includes cosmetics – 46 percent
- Medical Device and Radiological establishments –28percent
- Animal drug and feed establishments – 12 percent
- Human Drug establishments (includes Medical Gas) – 11 percent
- Biological establishments – includes blood banks – 3 percent
- Bioresearch Monitoring Establishments – 5 percent

Industry Highlights:

Major firms:

- Drugs: JHP Pharmaceuticals, Pharmacia and Upjohn Co. Div. of Pfizer, Dow Chemical, Perrigo, Albemarle Corporation, Vertellus Health and Specialty Products, Caraco Pharmaceutical.
- Foods: Mead Johnson Nutritionals, Ross Laboratories, Gerber Products, Kellogg Co., Post Cereals.
- Devices: Dow Corning, Stryker Instruments, Terumo Cardiovascular Systems Corp., Atek Medical Manufacturing, Amigo Mobility, Tri–State Hospital Supply.
- Biologics: Emergent BioDefense Operations Lansing (formerly Bioport, sole source of Anthrax vaccine), American Red Cross National Testing Laboratory.
- Imports: Detroit District ports of entry include airports, seaports, and border crossings along the Canadian border. FDA–regulated commodities entering

through these ports include food, drugs, medical devices and radiological products, biologics and cosmetics.

Contracts & Partnerships*:*

State Contracts

Michigan Department of Agriculture and Rural Development

- Conduct medicated feed mill and BSE rule inspections
- Conduct follow up investigations of violative drug tissue residues of food animals detected at the time of slaughter.
- Conduct food safety inspections (410 Inspections in FY10).
- Egg Rule Contract (New FY–11)

Michigan Department of Health

- Conduct inspections of mammography facilities.

State Partnerships

Michigan Department of Agriculture

- Implement an inspection plan to assure quality of non–Interstate Milk Shippers dairy products, other foods & drinks produced at dairy plants.
- Collect animal feed samples for FDA pesticide residue analysis.

Michigan Department of Public Health

- Educate consumers about the risks and dangers of health fraud.

State Cooperative Agreements

- BSE
- Rapid Response Team

Fact Sheet – Minnesota

FDA Presence:

- 98 FDA employees in Minnesota
- Resident Post: International Falls
  Reports to: Minneapolis District: Minneapolis
  Reports to: Central Region, Chicago, Illinois

Industry Presence in State – 5,423 FDA-regulated establishments:

- Food establishments – includes cosmetics – 39 percent
- Medical device and Radiological establishments – 19 percent
- Animal drug and feed establishments – 34 percent
- Human drug establishments – 6 percent
- Biologic establishments – includes blood banks – 2 percent

Imports:

- There are 10 ports of entry in the State of Minnesota.
- FDA regulated import entries are predominantly human food whole grain and milled products and non–medicated feed on the Northern border. Entries made through the Minneapolis ports are predominately Medical Devices and human food with fewer human drugs, radiological products and ceramic ware.
- Minnesota FDA regulated import entries are predominantly handled out of the Minneapolis District Office and one Resident Post on the Canadian border – International Falls. Assistance may also be given by our Madison Resident Post as needed.

Industry Highlights:

- Leads the nation in production of sugar beets, green peas and sweet corn for processing, and turkeys
- Second in the nation in production of spring wheat, oats, dry edible beans, and canola. Other key crops/products include canola, corn, dry edible beans, sunflowers, soybeans, barley, potatoes, flaxseed, total cheese, American cheese, cheddar, milk, honey, milk cows, and hogs.
- Minnesota ranks sixth nationally in agricultural exports
- Minnesota is home to such major firms as Medtronic, General Mills, 3M, Pillsbury, Land 0'Lakes, Boston Scientific, and St. Jude Medical
- The University of Minnesota and the Mayo Clinic are very active in medical bio–research

Contracts & Partnerships:

State Contracts

Minnesota Department of Agriculture

- Conduct GMP inspections of licensed medicated feed mills and BSE inspections at licensed and unlicensed feed facilities.
- Conduct food safety inspections, seafood HACCP, juice HACCP, LACF, and elevator inspections.
- Conduct follow–up investigations of first time violators of tissue residues in food animals.

Minnesota Department of Health

- Conduct MQSA audits of mammography facilities.

State Cooperative Agreements (Grants)

Minnesota Department of Agriculture

- BSE cooperative agreement to develop and improve the infrastructure of the state feed safety and BSE prevention programs.
- Food Safety Task Force to coordinate and address food safety and defense issues among regulated industry and regulators within the state.
- Food Protection Rapid Response Team Cooperative Agreement is to develop and sustain an all Food Hazards Rapid Response Team, encompassing both food and

feed protection programs, through a process to further enhance and build the infrastructure of State food protection programs.

Fact Sheet – Mississippi

FDA Presence:

- 7 FDA employees in Mississippi
- Resident Post: Jackson
  Reports to: New Orleans District (currently located in Nashville, TN), who
  Reports to: Southeast Region: Atlanta, Georgia

Industry Presence in State – 995 FDA-regulated establishments

- Food establishments – includes cosmetics – 45 percent
- Medical device and Radiological establishments – 25 percent
- Human drug establishments – 13 percent
- Animal drug and feed establishments – 13 percent
- Biologic establishments – includes blood banks – 4 percent

Industry Highlights:

- Two major ports of entry – Gulfport, Pascagoula. Most bananas imported into the U.S. are entered through the Port of Gulfport.
- Seafood – Mississippi's primary food industry includes Gulf shrimp and oysters from the coast and farm–raised catfish in the Delta.
- Agriculture – Poultry, timber, cattle, cotton, and soybeans are major agricultural crops.
- Ship building is a sizeable industry located in the city of Pascagoula.
- Human Drugs and Devices – Baxter operates a large LVP and device manufacturing facility in Cleveland.
- The Gulf Coast area was affected by Hurricanes Katrina & Rita in 2005. The industry is still recovering and will continue to be for a number of years.
- The Deepwater Horizon oil spill in 2010 significantly affected the Gulf Coast seafood industry.

Contracts & Partnerships:

State Contracts

Mississippi Department of Health

- Conduct food sanitation inspections.

State Partnerships

Mississippi Department of Health

- Share oversight and authority of regulated Interstate Milk Shippers, Milk Processing Plants, and IMS listed Single Service Container Manufacturing Plants in Mississippi.

- Cooperate in the evaluation of Mississippi's efforts to control contributing factors linked to food borne illness outbreaks.

Mississippi Departments of Marine Resources, Agriculture, and Health

- Establish a cooperative emergency response plan for natural disasters.

Special Programs

- Food Safety Task Force, which includes: MS Department of Health; MS Department of Agriculture and Commerce; MS Department of Marine Resources; MS State University Extension Service; MS Chemical Laboratory; MS Restaurant Association, and MS Farm Bureau.

Fact Sheet – Missouri

FDA Presence:

- 68 FDA employees in Missouri.
- Resident Posts: St. Louis (26), Springfield (4)
  Report to: Kansas City District, Lenexa, Kansas, who
  Reports to: Southwest Region, Dallas, Texas
- CDER National Division of Pharmaceutical Analysis (St. Louis – 38)

Industry Presence in State – 2,727 FDA-regulated establishments

- Food establishments – includes cosmetics – 41 percent
- Medical device and Radiological establishments – 25 percent
- Animal drug and feed establishments – 15 percent
- Human drug establishments – 15 percent
- Biologic establishments – includes blood banks – 4 percent

Industry Highlights:

- Key Agricultural Products:
  - Major crops include soybeans, corn and wheat
  - During CY 2000, the state produced 4.4 M head of cattle and 263 M chickens
- Bio–technology– Missouri ranks 11th among the top 25 biotechnology industry states in U.S.
- Major Veterinary Pharmaceutical Industry
- Southwest Import District handles imports for Missouri. The majority of products are medical devices and foods.
- The largest concentration of animal health industry in the world situated between Columbia (MO) and Manhattan (KS) aka "America's Animal Health Corridor"

Contracts, Partnerships & Local Activities:

State contracts

Missouri Department of Health and Senior Services

- Conduct inspections of mammography facilities.

- Conduct food safety inspections

State Partnerships

Missouri Department of Agriculture

- Conduct inspections and information sharing related to BSE.

Missouri Department of Health and Senior Services

- Coordinate the oversight of dairy manufacturing facilities
- Awarded to accomplish staphylococcus aureus survivability study

Local Activities

- Pharmaceutical Technical Exchange Association meets semi-annually and organized by FDA's Kansas City District to facilitate information exchange among the 200 member firms.
- KAN-DO cooperated with Missouri in response to major flooding along the Missouri river in 2011. The disaster continues to have major impact on crops and the agricultural industry in Iowa, Nebraska and Missouri.
- After 7th most deadly tornado in U.S. history struck Joplin, MO, cadres of KAN-DO investigators were dispatched to inspect FDA–regulated firms, including blood banks and food storage facilities.

Fact Sheet – Montana

FDA Presence:

- 6 FDA employees in Montana
- Resident Posts: Helena and Sweet grass
  Report to: Seattle District: Bothell, Washington,
  Reports to: Pacific Region: Oakland, California

Industry Presence in State – 1,090 FDA-regulated establishments

- Food establishments – includes cosmetics – 63 percent
- Medical device and Radiological establishments – 12 percent
- Human drug establishments – 9 percent
- Animal drug and feed establishments – 14 percent
- Biologic establishments – includes blood banks – 2 percent

Industry Highlights

- Production and processing of high protein grains and cereals is the leading agricultural activity, followed by beef.
- The largest General Mills facility is located in Billings, Montana.
- Over 270 grain elevators are subject to FDA inspectional jurisdiction.

Contracts & Partnerships

State contracts

Montana Department of Agriculture

- Conduct BSE inspections.

Montana Department of Public Health and Human Services

- Conducts inspections of mammography facilities and food facilities.
- Conducts food sanitation inspections.

State Partnerships

Montana Department of Agriculture

- The cooperative program encourages work sharing, data sharing, and educational exchange with respect to safety of animal feed.

Montana Department of Public Health and Human Services

- Establish working arrangements concerning mutual planning and sharing of reports for inspections, investigations, and analytical findings, related to food firms operating in Montana.

Fact Sheet – Nebraska

FDA Presence:

- 5 FDA employees in Nebraska
- Resident Post: Omaha (4)
- Reports to: Kansas City District, Lenexa, Kansas
- Reports to: Southwest Region, Dallas, Texas
- Reports to HQ: OA/OIM/DIO (1)

Industry Presence in State – 1,373 FDA-regulated establishments

- Food establishments – includes cosmetics – 44 percent
- Animal drug and feed establishments – 30 percent
- Medical device and radiological establishments –13 percent
- Human drug establishments –10 percent
- Biologic establishments – includes blood banks – 3 percent

Industry Highlights:

Key Agricultural State

- Major products include cattle, corn, hogs, soybeans, wheat, sorghum
- Major Industry involves food processing of state's farm output
- In 2004, produced 6.7 M cattle; 3 M hogs, 15 M chickens/broilers

Imports in Nebraska:

- Import entries are handled by the Southwest Import District. The primary products are fresh fruits and vegetables, candies, cosmetics and devices.

Contracts, Partnerships & Local Activities:

State Contracts

Nebraska Department of Agriculture

- Conduct inspections of the animal feed industry for compliance of GMP & BSE regulations.
- Conduct food safety inspections.

State Partnerships
Nebraska Department of Agriculture
- Share oversight of dairy manufacturing facilities.

Local Activities
- Nebraska is 1 of 8 states awarded funding under a cooperative agreement designed to enhance animal feed safety and BSE prevention programs.
- Nebraska Department of Agriculture has enrolled in FDA's nationally recognized Retail Food Standards Program.
- Nebraska Food Safety Task Force – Established under FDA-funded grant.

Fact Sheet – Nevada

FDA Presence:
- 3 FDA employees in Nevada
- Resident Posts: Reno, Las Vegas
  Reports to: San Francisco District, Alameda, California, who
  Reports to: Pacific Region, Oakland, California

Industry Presence in State – 842 FDA-regulated establishments
- Medical device and radiological establishments – 45 percent
- Food establishments – includes cosmetics – 25 percent
- Animal drug and feed establishments – 11 percent
- Human drug establishments – 14 percent
- Biologic establishments – includes blood banks – 5 percent

Industry Highlights:
- Growth of tourism and entertainment industry —– more than 7,000 food service establishments in Clark County (including Las Vegas) alone and expansion of food–related industries in the state.

Contracts & Local Activities:
State Contracts
Nevada Department of Health and Human Services
- Conduct inspections of food manufacturing facilities
- Conduct inspections of mammography facilities.
- Adopted the Manufacturing Food Program Standards in 2011

Local Activities

- Ongoing public affairs cooperation with Nevada Cooperative Extension Service, Nevada Dietetic Association, University of Nevada-Las Vegas and University of Nevada-Reno.
- FDA has worked closely with the Nevada State Health Division, Bureau of Health Protection Services, in oversight and training in areas of acidified foods and fluid milk, to provide for better coverage and more uniform application of laws and regulations.
- Nevada Food Protection Task Force – Established under FDA-funded grant.

Fact Sheet – New Hampshire

FDA Presence:

- 3 FDA employees
- Resident Post: Concord
  Reports to: New England District, Stoneham, Massachusetts who
  Reports to: Northeast Region, Jamaica, New York

Industry Presence in State – 606 FDA-regulated establishments:

- Food establishments – includes cosmetics – 42 percent
- Medical Device and Radiological establishments – 38 percent
- Human drug establishments – 14 percent
- Animal drug and feed establishments – 3 percent
- Biologic establishments – includes blood banks – 3 percent

Industry Highlights:

- New Hampshire's inventory makes up approximately 7% of the New England District Official Establishment Inventory of regulated firms, with an emphasis on foods and medical devices.
- Dairy farming and dairy products contribute about 31% of the state's total agricultural receipts.
- Sweet corn and potatoes are the leading vegetable crops while apples are the leading fruit crop.
- Included in New Hampshire's top 25 imported products are food items, such as frozen fish fillets, and medical device instruments.

State Contracts, Partnerships & Local Activities

None

Fact Sheet – New Jersey

FDA Presence:

- 103 employees in New Jersey
- Resident Posts: Voorhees, North Brunswick

Report to: New Jersey District, Parsippany, New Jersey
Reports to: Central Region, Chicago, Illinois

Industry Presence in State – 5,145 FDA-regulated establishments

- Food establishments – includes cosmetics – 47 percent
- Medical Device and Radiological establishments – 33 percent
- Human Drug establishments – 16 percent
- Biological establishments – includes blood banks – 2 percent
- Animal drug and feed establishments – 2 percent

Industry Highlights:

- New Jersey is recognized as the global epicenter of the pharmaceutical industry, with 15 of the world's 25 largest pharmaceutical companies having major facilities there. Also home to more pharmaceutical companies than any other state in the country, or any other country in the world.
- Throughout the 1990's, NJ-based pharmaceutical companies discovered and developed more than 1/3 of new drugs approved by FDA and are responsible for over 40% of the prescription medicine sales in the U.S.
- The medical device industry produces approximately 8% of U.S. medical technology sales.
- NJ also has a large and thriving seafood industry and is home to
    - numerous major food-processing companies.

Contracts & Partnerships:

State Contracts

New Jersey Department of Health and Senior Services

- Conducts over 400 food safety inspections, including seafood and juice HAACP inspections.

New Jersey Department of Environmental Protection

- Conducts inspections of mammography facilities

New Jersey Department of Agriculture

- Conducts follow up investigations of violative tissue residues in food animals found at the time of slaughter.
- Conduct inspections of feed mills and feed generators for compliance with medicated feed and BSE–related requirements.

State Partnerships

New Jersey Department of Health and Senior Services

- Training and equipment to enhance capabilities to conduct food safety inspections.
- Public health and food safety educational projects to increase awareness and protect consumers from unsafe food handling practices

New Jersey Department of Agriculture

- Educational project to enhance farmers dairy cattle medication record keeping and prevention of pathogen related illness from dairy herds

New Jersey Department of Environmental Protection

- Equipment and supplies to enhance collection and analysis of agricultural food commodities for pesticide levels.

Fact Sheet – New Mexico

FDA Presence:

- 3 FDA employees in New Mexico.
- Albuquerque Resident Post with2 employees reports to: Denver District Office in Denver, Colorado
- Denver District Office Reports to SW Regional Office in Dallas Texas
- Santa Teresa Resident Post with 1 employee and Columbus Resident Post with 0 employees report to Southwest Import District in Dallas, Texas
- Southwest Import District Reports to the Southwest Regional Office in Dallas Texas

Industry Presence in State – 833 FDA-regulated establishments

- Food establishments – includes cosmetics – 45 percent
- Human drug establishments – 20 percent
- Medical device and Radiological establishments – 18 percent
- *Animal drug and feed establishments – 12 percent*
- Biologic establishments – includes blood banks – 5 percent

Industry Highlights:

- Cattle and dairy products are major animal products of New Mexico.
- Limited, scientifically controlled dry land farming prospers alongside cattle ranching. Major crops include hay, nursery stock, pecans, and Chile peppers. Hay and sorghum top the list of major dry land crops. Farmers also produce onions, potatoes, and dairy products. New Mexico specialty crops include pinon nuts, pinto beans, and chilies.
- Industrial output, centered around Albuquerque, includes electric equipment, petroleum and coal products, food processing, printing and publishing, and stone, glass, and clay products. Defense–related industries include ordnance. Important high–technology industries include lasers, data processing, and solar energy.
- Imports in New Mexico: The Southwest Import District (SWID in Dallas) received 93,605 line entries during FY 2010 through New Mexico ports of entry. The primary imported products are alcoholic beverages and seafood.

Contracts and Partnerships:

State Contracts

New Mexico Department of Agriculture and Environmental Services

- Conduct inspections of medicated feed mills for safety and BSE control.

New Mexico State University

- Conduct scientific review of rapid test methods for validity and potential use in FDA Laboratories for regulatory screening

State Partnerships

New Mexico Department of Agriculture

- Conduct federal compliance testing of new assemblies or re–assemblies of x–ray equipment.

New Mexico Departments of Health, Agriculture, Environment, Livestock; Albuquerque City Health Department, Bernalillo County Environmental Health Department; NM Food Producers/Processors Association; NM University Cooperative Extension Service; and other industry and consumer groups

Formalize ongoing cooperative program to educate regulators, industry & consumers on HACCP, food safety principles, & develop/implement statewide HACCP training plan.

Fact Sheet – New York

FDA Presence:

- 407 FDA employees in New York State
- Resident Posts: Albany, Alexandria Bay, Binghamton, Champlain, Central Islip, Massena, New Windsor, Ogdensburg, Rochester, Syracuse, Port Elizabeth, NJ and White Plains, and Buffalo. 2 permanent offices at the Port of Buffalo (Peace Bridge and Lewiston Bridge)
  Report to: New York District, Jamaica NY (238 District employees) who
  Reports to: Northeast Region, Jamaica, NY
  Regional Office (12 employees), Northeast Regional Laboratory (130 employees), NY who reports to: Northeast Region
  HQ Employees: OIM (14), OFS (4), DFFI (8), DCMO (1)

Industry Presence in State – 10,215 regulated establishments

- Food establishments – includes cosmetics – 43 percent
- Medical Device and Radiological establishments – 34 percent
- Human drug establishments – 12 percent
- Animal drug and feed establishments – 8 percent
- Biologic establishments – includes blood banks – 3 percent

Industry Highlights:

- Imports – New York District ports of entry include airports, a seaport (located in Port Elizabeth, NJ), and numerous border crossings along the Canadian border. About 20% of the FDA regulated commodities enter the country through New York. Cheese, cosmetics, and active pharmaceutical ingredients are the top three high volume commodities. An international postal facility at JFK Airport requires New York District surveillance activity to regulate a significant volume of pharmaceutical entries. Another facility is located in Secaucus, NJ where mail from ocean borne carriers is handled. Along the Canadian Border we are successful in

improving our effectiveness in import coverage by leveraging with the NY State Department of Agriculture and Markets, the Canadian Food Inspection Agency, Health Canada and with other government agencies including, Customs and Border Protection, USDA, Fish and Wildlife Service and the US Postal Service.
- Generic drugs – New York supports a significant generic drug industry.
- Bioresearch – A significant number of clinical investigators and Institutional Review Boards affiliated with NYC metropolitan hospitals.
- Dairy – New York is one of the lead dairy states in the country.
- Livestock – New York receives a significant number of reports on violative residues in food animals detected at the time of slaughter from the USDA.
- Food – New York is the home of a highly visible food interstate conveyance sanitation program at the airports, rail and bus transportation locations. Food processors would include smoked fish, seafood, vegetables and cheese.
- There were 3,793,248 line entries of FDA–regulated products that were imported through the New York ports of entry through August 15, 2011; 4,545,760 line entries of FDA regulated products are projected to come through New York ports by the end of FY 2011.

Contracts & Partnerships:

State contracts

New York Department of Agriculture and Markets
- Conducts sanitation, seafood HACCP, juice HACCP, LACF/AF, BSE, medicated feed and tissue residue inspections.
- NYSDAM is in phase III of the food audit process and is responsible for conducting audits of its own inspectors.

New York State Department of Health
- Conduct inspections of mammography facilities.

State Partnerships

New York Department of Agriculture and Markets
- Coordinate the food protection efforts to reduce consumer risk, eliminate duplication, define regulatory roles, and improve communication.
- Provides information on State initiated recalls.
- Collects food samples for pesticide analysis.

Other
- Conduct inspections of mammography facilities by NY City inspectors.
- Enhanced collaborative efforts with Customs and Border Protection resulting in the detection of entries previously circumventing entry review process.
- NYSDAM and FDA work together to halt the entry and distribution of adulterated foods of import origin. This effort includes the sampling of imported foods encountered by NYSDAM in the domestic marketplace for ultimate submission to FDA for analysis. When a violation is confirmed, NYSDAM will initiate the appropriate regulatory action on the market while FDA will initiate an Import Alert to prevent future entries of the violative product.

- Collaborate with the Office of the Canadian Consulate General to conduct periodic new exporter seminars, using education as a means to achieve compliance. The Consulate coordinates logistics regarding meeting sites, reproduction of handouts, and solicitation of attendees. FDA provides an instructor and materials.
- Leveraging with the Canadian Food Inspection Agency and Health Canada to share information when high risk violations are encountered in products crossing the border. This offers enhanced consumer protection to both US and Canadian Consumers.

Fact Sheet – North Carolina

FDA Presence:

- 18 FDA employees in North Carolina
- Resident Posts: Asheville, Charlotte, Greensboro, Greenville, Raleigh, and Wilmington
  Report to: Atlanta District, Atlanta, Georgia, who
  Reports to: Southeast Region, Atlanta, Georgia
- HQ employee: ORO–1

Industry Presence in State – 2,801 FDA–regulated establishments

- Food establishments – includes cosmetics – 37 percent
- Medical Device and Radiological establishments – 29 percent
- Human Drug establishments – 18 percent
- Animal Drug and Feed establishments –11 percent
- Biological establishments – includes blood banks – 4 percent
- Tobacco Products – 1 percent

Industry Highlights*:*

- Major international drug firms located in Research Triangle Park area
- Significant medical device industries
- Land ports in Charlotte (15,000 entries per annum), Raleigh–Durham (27,455 entries per annum), and Greensboro (4,000 entries per annum)—major products include foods, drugs, and medical devices. Sea ports in Wilmington (3,600+ entries per annum)—major products include animal feeds and commodities such as grapes, and Morehead City–Beaufort (less than 25 entries per annum)—major products include dry bulk animal feed and human food.

Contracts, Partnerships & Local Activities*:*

State Contracts

North Carolina Department of Agriculture

- Conduct inspections of feed mills for medicated feed and BSE
- Conduct food sanitation inspections
- Conduct Egg Facility Inspections

North Carolina Department of Environment & Natural Resources

- Conduct inspections of mammography facilities.
- Conduct inspection of fish & fisheries products processors for compliance with the Hazard Analysis and Critical Control Points (HACCP) regulations.

State Partnerships

North Carolina Department of Agriculture and Consumer Services

- Conduct joint statutory inspectional coverage of the medical gas Manufacturing and repacking industries.
- Joint NCDA&CS–FDA Rapid Response Team for food emergencies

Local Activities

North Carolina Food Safety and Defense Task Force

Fact Sheet – North Dakota

FDA Presence:

- 8 FDA employees in North Dakota
- Resident Posts: Dunseith, Fargo, Pembina and Portal
  Report to: Minneapolis District, Minneapolis, Minnesota
  Reports to: Central Region, Chicago, Illinois

Industry Presence in State – 1,438 FDA-regulated establishments

- Food establishments – includes cosmetics – 52 percent
- Animal drug and feed establishments – 41 percent
- Medical Device and Radiological establishments –4 percent
- Human drug establishments – 2 percent
- Biologic establishments – includes blood banks – 1 percent

Imports:

- There are 22 active ports of entry in North Dakota.
- FDA regulated import entries are predominantly human food whole grain and milled products and non–medicated animal feed.
- Regulated import entries are predominantly handled out of the 2 ND Northern border ports in Pembina and Portal.

Industry Highlights:

- Agriculture – North Dakota is the overall leader of wheat production and the top producer of durum wheat and spring wheat. The State also leads the nation in the production of honey, barley, lentils, sunflowers, dry edible beans, dry edible peas, flaxseed, and canola. Other key crops include oats, potatoes, and sugar beets.
- Raising elk, deer and buffalo for meat is a part of the agri-industry.

Contracts & Partnerships:
State Contracts
North Dakota Department of Agriculture

- Conduct GMP inspections of licensed feed mills, and BSE inspections of licensed and unlicensed feed facilities.
- Conduct follow up investigations of first time violators of tissue residues in food animals.

North Dakota Department of Health

- Conduct inspections of mammography facilities.

Fact Sheet – Ohio

FDA Presence:

- 162 FDA employees in Ohio
- Resident Posts: Cincinnati South, Brunswick (Cleveland area), Columbus, and Toledo
  Report to: Cincinnati District, Cincinnati, Ohio
  Reports to: Central Region, Chicago, Illinois
- Forensic Chemistry Center: Cincinnati, Ohio
- The Cincinnati District Office and the Forensic Chemistry Center are separate organizations, each report to the Central Region in Chicago, IL.

Industry Presence in State – 4,995 FDA-regulated establishments

- Food establishments – includes cosmetics – 44 percent
- Medical Device and Radiological establishments – 32 percent
- Human drug establishments – 13 percent
- Animal drug and feed establishments – 7 percent
- Biologic establishments – includes blood banks – 4 percent

Industry Highlights:

- Foods- Ohio is headquarters to many national and international food and flavor firms. The State is a leader in many areas including: frozen specialty foods, pet food, ketchup and is the nation's largest producer of Swiss cheese and second in egg production. The world's largest pizza, soup and yogurt plants call Ohio home.
- Agriculture- Ohio includes a significant agricultural base including "mega–farms".
- Drugs- Ohio is the home of numerous pharmaceutical facilities.
- Devices: Ohio is home to firms which are worldwide supplies of x–ray equipment, wheelchairs and "sterilizers."

Contracts, Partnerships & Local Activities:
State Contracts
Department of Agriculture

- Conduct inspections of feed mills for medicated feed and BSE.
- Conduct human food sanitation inspections including Seafood & Juice HACCP.

- Conduct follow up investigations of violative drug residues in food animals at the time of slaughter.
- Conduct inspections for compliance with the Egg Rule

Department of Health

- Conduct inspections of mammography facilities.

State Partnerships

Ohio Department of Agriculture (ODA)

- Establish training for state employees in analytical procedures and joint inspections.
- Joint training of the livestock industry on producing and marketing livestock without drug residues.
- Participated in FDA eSAF training.
- Participated in Better Process Control School.
- Partnered to provide Seafood and Juice HACCP training for industry.
- Participated in Food Inspections including environmental sampling.

Ohio Department of Health (ODH)

- Conduct federal compliance testing of new or re–assemblies of x–ray equipment.

Local Activities

- CIN–DO holds an annual partnership meeting with ODA Food Division, ODA Laboratories and ODH.
- CIN–DO attends quarterly FORC–G Meetings with State and local officials on food safety issues.

Fact Sheet – Oklahoma

FDA Presence:

- 4 FDA employees in Oklahoma
- Resident Posts: Oklahoma City and Tulsa
  Report to: Dallas District, Dallas, Texas who
  Reports to: Southwest Region, Dallas, Texas
- Import entries are handled from the Southwest Import District office in Dallas, Texas and with the assistance of the staff located at the Dallas District Oklahoma Resident Posts.

Industry Presence in State – 2,047 FDA-regulated establishments

- Food establishments – includes cosmetics – 55 percent
- Animal drug and feed establishments – 18 percent
- Medical device and Radiological establishments – 14 percent
- Human drug establishments – 10 percent
- Biologic establishments – includes blood banks – 3 percent

Industry Highlights:

- Food - Oklahoma is a major egg production state and has several Tyson poultry production facilities. Also the home of Bama® pies.
- Grains – Oklahoma produces a significant amount of winter wheat, peanuts, soybeans, and seeds for sprouts.
- Farming – Oklahoma is a major producer of feeder cattle, milk and catfish.
- Medical devices – Oklahoma has major device manufacturers including Smith & Nephew Endoscopy, dental implants and kidney dialysis supplies.
- Dietary Supplements – Oklahoma houses Shaklee manufacturing.
- Bioresearch – the University of Oklahoma, School of Medicine generates work in the bioresearch program area.
- Southwest Import District- The entries received through Oklahoma are reviewed by SWID Investigators. The primary imported products are devices and processed foods.

Contracts, Partnerships and Local Activities:

State Contracts

Oklahoma Department of Health

- Conduct inspections of mammography facilities.
- Conduct inspections of food manufacturing and storage facilities

Oklahoma Department of Agriculture

- Conduct inspections of feed mills to determine compliance with BSE Rule.

State Partnerships

Oklahoma Department of Agriculture

- Share oversight and authority of regulated dairy manufacturing facilities

Dallas District Public Affairs Specialists respond to consumers and media inquiries and conduct consumer education outreach to diverse constituents, including Native American tribes.

Southwest Import District Public Affairs Specialist focuses on Import issues. Conducts education and outreach to the Import industry, State and other government officials and supports border health issues.

Fact Sheet – Oregon

FDA Presence:

- 26 FDA employees in Oregon
- Resident Posts: Portland and Beaverton who
  Report to: Seattle District, Bothell, Washington who
- Reports to: Pacific Region, Oakland, California

Industry Presence in State – 2,643 FDA-regulated establishments

- Food establishments – includes cosmetics – 63 percent
- Medical device and Radiological establishments – 21 percent
- Human drug establishments – 8 percent
- Animal drug and feed establishments – 6 percent
- Biologic establishments – includes blood banks – 2 percent

Industry Highlights

- Oregon agriculture, fisheries, and food processing activities exceed $5.25 Billion in commerce.
- Biotechnology, medical device, and medical research activities are growing industries

Contracts, Partnerships & Local Activities

State Contracts

Oregon Department of Agriculture

- Conduct food sanitation inspections.
- Conduct follow–up investigations of violative tissue residues in food animals at the time of slaughter.
- Conduct BSE inspections.

Oregon State Department of Human Resources

- Conduct inspections of mammography facilities

State Partnerships

Oregon State Department of Agriculture

- Share information and training to enhance consumer protection in food safety.

Local Activities

FDA representatives participate in:

- Interagency Food Safety Team
- Oregon Alliance Working for Antibiotic Resistance Education
- Collaborative activity with the Northwest Food Processor Association to promote food defense awareness

Fact Sheet – Pennsylvania

FDA Presence:

- 113 employees in Pennsylvania
- Resident Posts: Harrisburg, Pittsburgh, Wilkes Barre
  Report to: Philadelphia District, Philadelphia
  Reports to: Central Region, Chicago, Illinois

Industry Presence in State – 5,153 FDA–regulated establishments

- Food Establishments – includes cosmetics – 43 percent

- Medical Device and Radiological establishments – 29 percent
- Human Drug establishments – 17 percent
- Animal drug and feed establishments – 6 percent
- Biological establishments – includes blood banks – 5 percent

Industry Highlights:
- Pennsylvania has a large pharmaceutical industry.
- Pennsylvania is one of the Nation's largest producers of dairy products, mushrooms, poultry and eggs.

Contracts, Partnerships & Local Activities:
State Contracts:
PA Department of Agriculture (PDA)
- Conducts inspections of medicated feed mills, including coverage of BSE.
- Conducts inspections of mammography facilities
- Conducts inspections of 100–150 food manufacturers in PA annually.

State Partnerships:
PA Food Safety Council (PFSC), a partnership with the state and local governments, academia, industry and USDA to address food safety issues.
PA Department of Agriculture:
- Coordinates regulatory activities enforcing the Nutrition Labeling & Education Act.
- Coordinates work planning and inspectional activities to assure all non–medicated feed mills in PA are inspected yearly, for compliance with regulations designed to prevent the introduction of BSE

PA Department of Agriculture and the PA Department of Health:
- Assure consumers that eggs from Pennsylvania are of minimal risk of food–borne disease from Salmonella enteriditis.

Memorandum of Understanding (MOU):
- PA Dept. of Agriculture, PA Dept. of Health and a number of egg producers for egg inspections under the PA Egg Quality Assurance Program.
- PA Department of Agriculture – Tissue Residue

Fact Sheet – Puerto Rico

- 80 FDA Full Time employees in Puerto Rico
  3 Part–Time Students
  2 Science Advisors
- Resident Posts: Aguada, Ponce and US Virgin Islands
- National Drug Specialty Laboratory– Accredited in May 2006 under ISO 17025.
  Reports to: San Juan District Office,
  Reports to: Southeast Region, Atlanta, GA
- Office of Criminal Investigations (OCI): 6 FT employees– reports to OCI FLA–FO

Industry Presence in State – 1,499 FDA–regulated establishments

- Food establishments – includes cosmetics – 52 percent
- Medical device and radiological establishments – 25 percent
- Human drug establishments – 15 percent
- Animal drug and feed establishments – 5 percent
- Biologics establishments – includes blood banks – 3 percent

Industry Highlights:

- Puerto Rico has the 3rd largest bio–manufacturing capacity in the world with 53% of PhRMA affiliates
- In 2001, P.R. ranked 1st in percent share of pharmaceutical global exports and 5th in percent share of pharmaceutical global production. In 2004, pharmaceutical exports reached $35.2 billion or 64% of all island exports.
- In 2008, 13 of the top 20 ethical prescription drug products sold in USA as well 13 of the top 20 Rx products sold globally were manufactured in PR
- Major manufacturers include: Astra Zeneca/IPR, Pfizer, Eli Lilly, Abbott, Bristol Myers Squibb, Merck Sharp & Dhome, Biovail, Amgen, Procter & Gamble, Schering–Plough, J&J Pharmaceutical Partners (Janssen, McNeil, Ortho), Legacy, Roche Pharma, and Warner–Chilcott.
- Other companies are moving part of their process development and research to PR including Bristol Myers Squibb, Abbott and Becton Dickinson.
- PR has a sizable presence of internationally recognized medical device manufacturing companies which has increased to about 80 in the last few years- approximately 50% of all pacemakers and defibrillators sold in the US mainland are manufactured here.
- San Juan is a significant trans–shipment point for cargo – fresh produce, non–perishable goods, active pharmaceutical ingredients and device parts
- Puerto Rico has the largest, noncontiguous Foreign Trade Zone (FTZ) system in the United States.
- There is one International Mail Facility located in Carolina, PR.
- In 2006, biologics produced in PR sold over $16 billion in the US alone. This, along with over $4 billion invested in biotechnology plants over the past 5 years, makes PR one of the fastest growing life sciences center in the world. 25% of the world's biological manufacturing capacity is located in Puerto Rico.

International Work:

- SJN– District operational staff is fully bilingual. 50% of our chemists and experienced investigators are active in the foreign inspection cadre. Our staff also plans and supports educational activities on QSR and GMP for representatives of regulatory agencies throughout Latin America and the Caribbean, through organizations such as ISPE, PDA, Pharmaceutical Industry Assoc. of PR, PAHO, foreign government organizations and Academia. Our employees travel to South and Central America, Mexico, Europe, Asia, and Canada, among others.

Contracts, MOUs & Partnerships:

- P.R. Department of Health– Environmental Health Division:
  - Contract to conduct inspections of food manufacturers for sanitation
  - Pilot to share violative food inspections cases to leverage enforcement.
  - MOU: Confers embargo and seizure powers to SJN–DO for inspection of regulated goods in response to natural disasters.
  - Publication of the Federal Food Code Handbook in Spanish for Health Department to train their inspectors. 200 graduated in December 2006.
  - Published a summary of the Food Code, both in Spanish and English, to train Puerto Rico and USVI food establishments' staff.
- P.R. Department of Health– Radiological Health Division:
  - Contract to conduct inspections of mammography facilities.
- P.R. Department of Agriculture:
  - MOU on emergency relocation, complying with COOP requirements.
  - Agrological Lab accepted into FERN.
- P.R. Department of Consumer Affairs
  - Pilot to share information on violative dietary supplements and unapproved drugs, particularly in the area of ED and sexual enhancement drugs.

Fact Sheet – Rhode Island

FDA Presence:

- 6 FDA employees in Rhode Island
- Resident Post: Riverside
  Reports to: New England District, Stoneham, Massachusetts, who
  Reports to: Northeast Region, Jamaica, New York

Industry Presence in State – 600 FDA–regulated establishments

- Food establishments – includes cosmetics – 45 percent
- Medical Device and Radiological establishments – 35 percent
- Human drug establishments – 15 percent
- Animal drug and feed establishments – 2 percent
- Biologic establishments – includes blood banks – 3 percent

Industry Highlights*:*

- Rhode Island is responsible for 7% of the District's Official Establishment Inventory of FDA–regulated firms with an emphasis on foods and medical devices.
- Milk is the third–ranking agricultural product of the state. Dairy products account for about 5% of the total agricultural receipts
- Beef cattle, hogs, and chickens are raised in the state. Chicken eggs produce important revenue.
- Sweet corn is generates about 6% of the state's total agricultural receipts.

- The fishing industry includes a variety of fish, mollusks and shellfish. Lobster is the most valuable of these. Other important catches are anglerfish, clams, cod, flounder, scup, squid, whiting and yellowfish.

State Contracts and Partnerships

State Contracts

Rhode Island Department of Health

- Conduct food sanitation inspections and seafood HACCP (Hazard Analysis and Critical Control Point) inspections.
- Conduct inspections of mammography facilities.
- Participate in FDA's Manufactured Food Regulatory Program Standards.
- Rhode Island has a Food Safety Task Force in which FDA is a participant. They also hold meetings and training sessions sponsored by the Food Safety Task Force in which FDA participates.
- RI is also putting together a strategic plan to meet Healthy People 2020 Health Objectives for food safety. Once the draft plan is complete, the State will obtain input from the task force on how best to reduce illness in each of the target areas.

Fact Sheet – South Carolina

FDA Presence:

- 12 FDA employees in South Carolina
- Resident Posts: Charleston, Columbia, and Greenville
  Report to: Atlanta District, Atlanta, Georgia, who
  Reports to: Southeast Region, Atlanta, Georgia

Industry Presence in State – 1,330 FDA–regulated establishments

- Food establishments – includes cosmetics – 48 percent
- Medical Device and Radiological establishments – 27 percent
- Human Drug establishments – 13 percent
- Biological establishments – includes blood banks – 4 percent
- Animal Drug and feed establishments – 8 percent

Industry Highlights:

- Major egg industry
- Major food supplement manufacturer
- Charleston ranks 4th in the nation among the largest container seaports- 84,500+ entries annually
- major commodities include human foods and medical devices

Contracts, Partnerships & Local Activities*:*

State Contracts

South Carolina Department of Agriculture

- Conducts inspections of food manufacturers for sanitation.

South Carolina Department of Health & Environmental Controls

- Conduct inspections of mammography and soft drink/bottled water facilities.

Local Activities

- South Carolina Interagency Food Safety and Defense Council

Fact Sheet – South Dakota

FDA Presence:

- 2 FDA employees in South Dakota
- Resident Post: Sioux Falls
  Reports to: Minneapolis District, Minneapolis, Minnesota
  Reports to: Central Region, Chicago, Illinois

Industry Presence in State – 1,104 FDA–regulated establishments

- Animal drug and feed establishments – 44 percent
- Food establishments – includes cosmetics – 42 percent
- Medical device and Radiological establishments – 8 percent
- Human Drug establishments – 4 percent
- Biologic establishments – includes blood banks – 2 percent

Imports:

- 1 active port of entry
- FDA regulated import entries are primarily food, food additives, cardiovascular and radiological devices.
- The South Dakota FDA regulated import entries are handled out of the Minneapolis District FDA office with assistance from the Madison Resident Post as needed.

Industry Highlights:

- Agriculture- Ranks 2nd in the production of alfalfa hay, sunflowers, and flaxseed and honey.
- Other key crops include wheat, durum wheat, spring wheat, winter wheat, wheat, corn, hay, sorghum, soybeans, oats, and proso millet.
- Cattle and sheep ranching are also a significant.

Contracts:

State Contracts

- South Dakota Department of Agriculture
- Conduct GMP inspections of licensed feed mills and BSE inspections of feed facilities.
- Conduct follow up investigations of first time violators of tissue residues in food animals.

- South Dakota Department of Environment and Health
- Conduct inspections of mammography facilities.

Fact Sheet – Tennessee

FDA Presence:

- 81 FDA employees in Tennessee
- Office/Resident Posts: Nashville, Chattanooga, Knoxville and Memphis, Report to: New Orleans District (currently located in Nashville, TN), who Reports to: Southeast Region, Atlanta, Georgia

Industry Presence in State – 3,105 FDA–regulated establishments

- Medical device and radiological establishments – 30 percent
- Food establishments – includes cosmetics – 38 percent
- Human drug establishments – 16 percent
- Biologic establishments – includes blood banks – 5 percent
- Animal drug and feed establishments – 11 percent

Industry Highlights:

- Memphis import operation reviews entries of regulated products for Fed–Ex, the nation's largest overnight courier service.
- Major medical research centers at universities and hospitals in Memphis and Nashville and a national biologics testing laboratory and several regional blood banking operations
- Major oral antibiotic manufacturer and 2 major implantable device manufacturers
- Rapidly expanding freshwater prawn/shrimp industry and 10 Paddlefish roe (domestic caviar) processors
- Industry in the Nashville area was affected by massive flooding in May 2010, and is still recovering.

Contracts & Partnerships:

State contracts

Tennessee Department of Agriculture

- Conduct sanitation inspections of food manufacturers
- Conduct BSE/ feed mill inspections

Special Programs

Tennessee Food Safety Task Force, since 2002. The TN Departments of Agriculture, Inspection & Veterinary Services; TN Department of Health Epidemiologist; TN Department of Education; Univ. of TN Agricultural Extension Service and several industry representatives meet quarterly for program planning and information sharing.

Fact Sheet – Texas

FDA Presence:

- 224 FDA employees in Texas
  - Dallas District (100),
  - Southwest Import District (SWID) (86),
    - Report to: Southwest Region (22),
- FDA has Import and Domestic Resident Posts in Texas:
  - Import Resident Posts: Dallas–Fort Worth International Airport, Houston Seaport/Airport, Yselta/El Paso, Laredo/Columbia/Lincoln–Juarez, Eagle Pass/ Del Rio, Rio Grande City, Pharr, Brownsville, San Antonio
  - Domestic Resident Posts: Austin, El Paso, Houston, Ft. Worth, San Antonio
- Office of Regulatory Affairs HQ (4) and Office of Shared Services/Office of Information Management (12)

Industry Presence in State – 9,760 FDA–regulated establishments

- Food establishments – includes cosmetics – 47 percent
- Medical devices and Radiological establishments – 20 percent
- Human drug establishments –12 percent
- Animal drug and feed establishments – 17 percent
- Biologics establishments – includes blood banks – 4 percent

Industry Highlights:

- Seafood – Texas Gulf Coast is the home of numerous seafood firms.
- Imports into Texas – Primary products are fresh produce, seafood, processed foods, and medical devices.
- Human Drugs and Medical Devices – Texas is the home of Alcon, Allergan, Abbott, Hoechst–Celanese, Mentor, Hospira and Cyberonics.
- The Texas Panhandle has a large number of feedlots, slaughter facilities, and rendering operations.

Contracts, Partnerships & Local Activities:

State Contracts (all with the Texas Department of State Health Services)

- Conduct inspections for food sanitation
- Conduct inspections for milk safety
- Conduct inspections for reported violative residue in food animals at slaughter
- Conduct inspections of mammography facilities
- Conduct medical device inspections

State Partnerships and Cooperative Agreements

Texas Department of Health

- Examine, sample and test imported foods, cosmetics, drugs & medical devices and take appropriate action
- Conduct inspections of medical gas and OTC drug manufacturers and repackers

- Examine, sample and test imported foods, cosmetics, drugs & medical devices and take appropriate action
- Conduct inspections of new x–ray assemblies and re–assemblies
- Coordinate inspections of dairy manufacturing facilities
- Texas received a Rapid Response Team grant

Office of the Texas State Chemist – Feed and Fertilizer Control Service
- Coordinate inspections of animal feed production and compliance with BSE rule consumer education outreach to diverse constituents.

Southwest Import District Public Affairs Specialist primary focus is on import issues. SWID PAS conducts education and outreach to the import industry, state, and other government officials and supports border health programs.
Dallas District Public Affairs Specialists respond to consumers and media inquiries and conduct consumer education outreach to diverse constituents, including a large number of Hispanics.

Fact Sheet – U.S. Virgin Islands

FDA Presence:
- 1 Full Time FDA employee (Resident in Charge) in US Virgin Islands
- Resident Post: St. Thomas
  Reports to: San Juan District Office
  Reports to: Southeast Region, Atlanta, GA

Industry Presence in State – 72 FDA–regulated establishments
- 100 FDA–regulated establishments in US Virgin Islands
  (Some firms are in more than one category)
- Food establishments – includes cosmetics – 71 percent
- Medical device and radiological establishments – 8 percent
- Human drug establishments – 15 percent
- Biologic establishments – includes blood banks – 3 percent
- Animal drug and feed establishments – 1 percent
- Tobacco Products – 2 percent
- Interstate Travel Program – 4 percent
- Import Operations:
  - International Mail Facility (1), located on St. Thomas;
  - Sea Container Ports (2); St. Thomas (1) and St. Croix (1)
  - Air Cargo (2): St. Thomas (1) and St. Croix (1)
  - Passenger Terminals (5): St. Thomas (2); St. Croix (2) and St. John (1)

Industry Highlights:
- 2 dairy farms.
- Charlotte Amalie is a major port for cruise ship stops.

- 1 International Mail Facility located in St. Thomas.
- Customs Service in the USVI is considered outside the Customs Territory of US, which it operates under the Danish Public Law 64. Import merchandise is carried out manually posing challenges in screening and targeting of import goods.
- Close working relations have been formed with the Federal and local government agencies including Customs and Border Protection, U.S. Postal Service, Drug Enforcement Agency, USVI Department of Health, USVI Department of Environmental Protection and Natural Resources; and the USVI Department of Consumer and Licensing.
- In Domestic Operations, the coordination of Recall Audit checks with the local USVI Health Department is crucial in that suspected adulterated products can be removed from the market on all 3 islands by virtue of joint collaboration and the use of local government embargo authority.

Contracts and Partnerships:

State Partnerships

- FDA's work, through our partnership with USVI Health Department, resulted in the adoption of two food safety laws in 2004: the Pasteurized Milk Ordinance and a modern Food Code. PMO is in abeyance.
- San Juan District has promoted use of experts within Puerto Rico to assist in the adoption of new laws and establishing a milk certification laboratory.
- The Commonwealth has provided training to USVI technologists on milk sampling and analyses, and agreed to analyze samples until USVI's milk certification lab is operational.
- Partners with the Departments of Health and Licensing and Consumers' Affairs to provide training on inspection techniques for inspectors.
- Negotiating establishment of MOU with the USVI Department of Health for granting of embargo power to FDA in case of emergencies.

Local Activities

The District's Public Affairs Office has developed and/or conducted:

- Food Defense/ALERT Outreach for Food Retailers and State Inspectors
- A brochure on Food Safety during emergencies
- Training on food safety and FSMA for government officials, academia, and industry
- Conference on diabetes and women
- Campaign on generic drugs

Fact Sheet – Utah

FDA Presence:

- 11 FDA employees in Utah
- Salt Lake City Resident Post reports to Denver District Office in Denver, Colorado
- Denver District Office reports to Southwest Regional Office in Dallas, Texas

Industry Presence in State – 1,365 FDA–regulated establishments

- Food establishments – includes cosmetics – 40 percent
- Medical device and radiological establishments – 25 percent
- Human drug establishments –19 percent
- Animal drug and feed establishments – 10 percent
- Biologic establishments – includes blood banks – 6 percent

Industry Highlights:

- Agriculture is dependent on irrigation, and more than —3/4 of farm income is from livestock and livestock products. Hay is the most important crop, followed by wheat, barley, and corn (maize).
- Following the national trend, farm employment and the number of farms in Utah have declined since 1960, but productivity has increased. Almost —3/4 of Utah's farm income comes from livestock products, the remainder from field crops, fruit, and canning crops.
- Utah has a thriving biotechnology and medical device manufacturing industry and is home to several of the nation's largest disposable device manufacturers.
- Imports – The Southwest Import District (SWID located in Dallas) received 6,390 entry lines for fiscal year 2010. Primary products are cosmetics and medical devices. Imports assignments issued by SWID are handled by Denver district staff.

Contracts, Partnerships & Local Activities:

State contracts

Utah Department of Health

- Conduct inspections of mammography facilities.

Utah Department of Agriculture and Foods, Regulatory Services

- Conduct inspections of feed mills for medicated feed and BSE
- Conduct 75 inspections of food firms

State Partnerships

Utah Department of Agriculture & Food, Utah Department of Health and Industry

- Support the Utah Egg Quality Assurance Plan to ensure quality and safety of shell eggs.
- Conduct feedlot inspections (15 total) for compliance with the ruminant feeding rule.

Utah Department of Environmental Quality

- Conduct inspections of new x–ray assemblies or re–assemblies.

Fact Sheet – Vermont

FDA Presence:

- 6 FDA employees in Vermont
- Border Station: High gate Springs
  Reports to: New England District, Stoneham, Massachusetts, who

Reports to: Northeast Region, Jamaica, New York

Industry Presence in State – 621 FDA–regulated establishments

- Food establishments – includes cosmetics – 70 percent
- Medical Device and Radiological establishments – 12 percent
- Human drug establishments – 8 percent
- Animal drug and feed establishments – 9 percent
- Biologic establishments – includes blood banks – 1 percent

Industry Highlights:

- Vermont has 6% of the District's Official Establishment Inventory of FDA–regulated firms with a concentration in the food area.
- About 3/4 of Vermont's agricultural income is generated by the sale of dairy products.
- Other important livestock products are beef cattle and calves, chicken eggs, turkeys, and hogs.
- Leading vegetables grown in the state are sweet corn and potatoes. Apples are the largest fruit crop.
- Vermont is a leading maple–syrup producing state and also produces many specialty food products such as cheese, ice cream and sauces.
- Included in the State of Vermont's top 25 imported products include food items, such as chocolate prep, maple sugar, corn, and animal feed.

State Contracts and Partnerships*:*

State Contracts

Vermont Department of Agriculture

- Conduct follow–up inspections/investigations of violative drug tissue residues in food animals at the time of slaughter. All inspections covered BSE.

Vermont Department of Health

- Conduct inspections of mammography facilities.
- Conduct food sanitation inspections and juice Hazard Analysis and Critical Control Point (HACCP) inspections.
- Participate in FDA's Manufactured Food Regulatory Program Standards

Local Activities

- The State of Vermont participates in the Food Protection Task Force Conference.
- Representatives from the State also participated in:
    - NEFDOA meeting in Mystic, CT in May 2011
    - AFDO Seafood Hazards Guide Training in Providence, RI in June 2011.
    - FDA Northeast Region Food Protection Seminar in Portland, ME in August 2011

- The State of Vermont also participates in the FDA New England District Tissue Residue Reduction Task Force. This task force is a collaborative initiative between the District and the VT Agency of Agriculture focused on the prevention of Illegal drug residues in meat and edible tissues of animals produced in VT for human consumption. The Task Force areas of emphasis are centered on Industry Outreach and Education, Improving FDA and VT State Investigational Effectiveness, and Promoting Compliance Outcomes.

Fact Sheet – Virginia

FDA Presence:

- 37 FDA employees in Virginia
- Resident Posts: Falls Church, Portsmouth, Richmond, and Roanoke
  Report to: Baltimore District, Baltimore, Maryland
  Reports to: Central Region, Chicago, Illinois

Industry Presence in State – 3,177 FDA–regulated establishments

- Food establishments – includes cosmetics – 51 percent
- Medical device and Radiological establishments – 28 percent
- Human drug establishments – 9 percent
- Animal drug and feed establishments – 8 percent
- Biologic establishments – includes blood banks – 4 percent

Industry Highlights:

The industry in the state is very diverse and representative of the FDA national inventory including large, medium and small firms active in all FDA regulated product lines.

- Seafood
- Federal Food Service facilities
- Biotechnology firms
- Headquarters of the largest blood supplier in the United States.
- Imported products via the ports of Norfolk/Newport News and Dulles International Airport

Contracts & Partnerships:

State Contracts

Virginia Department of Agriculture and Consumer Services

- Conduct 3 inspections of feed mills
- Bovine Spongiform Encephalopathy (BSE)- Contract includes 41 inspections of feed manufacturers, retail operations, haulers
- Food/Seafood- Contract includes 470 inspections of food/seafood manufacturers, repackers, distributors, and warehouses

Virginia Department of Health

- Conduct inspections of mammography facilities.

State Partnerships
Virginia Department of Agriculture and Consumer Services

- Collect and analyze food commodities grown for pesticides and industrial chemicals.

Virginia Department of Health Professions

- Conduct testing of new and re–assembled x–ray equipment.

Fact Sheet – Washington

FDA Presence:

- 167 FDA employees in Washington
- Resident Posts: Blaine, Seattle, Spokane, Yakima, Oroville, and Tacoma
  Report to: Seattle District: Bothell, WA who
  Reports to: Pacific Region: Oakland, California
- Pacific Northwest Regional Laboratory: Bothell, who reports to Pacific Region

Industry Presence in State – 4,846 FDA–regulated establishments

- Food establishments – includes cosmetics – 63 percent
- Medical device and Radiological establishments – 19 percent
- Human drug establishments – 7 percent
- Animal drug and feed establishments – 9 percent
- Biologic establishments – includes blood banks – 2 percent

Industry Highlights

Washington leading industries include dairy, fruit, biotechnology, and medical devices. Washington ranks in the top 5 nationwide in production of 29 different agricultural products. Washington is one of the largest and most diversified food and agricultural exporters.

Contracts, Partnerships & Local Activities

State Contracts: Washington Department of Agriculture

- Conduct inspections for food sanitation.
- Conduct investigations of reported violative residues in food animals at the time of slaughter.
- Conduct BSE inspections.

Washington Department of Health

- Conduct inspections of mammography facilities. Conduct inspections of new X–ray assemblies or re–assemblies.

State Partnerships
Washington Department of Agriculture

- Coordinate the regulation for food safety by work sharing, data sharing and educational exchange, including all current and future inspectional and sampling contracts

- Coordinate the regulation of the fish and fishery products processing industry
- Participate in a cooperative program, which encourages work sharing, data sharing, and educational exchange concerning animal feed safety.

Local Activities

- Member of the Food Safety Review Council. The group works in partnership with the Department of Health in developing advisory technical interpretations of the state food service regulations and other matters.
- Member of the Washington State Subcommittee on Agricultural and Food Safety. The group works to reduce the vulnerability to a terrorist attack on agricultural industry and to improve coordination and collaboration among key partners.

Fact Sheet – West Virginia

FDA Presence:

- 3 FDA employees in West Virginia
- Resident Posts: Charleston and Morgantown
  Reports to: Baltimore District, Baltimore, Maryland
  Reports to: Central Region, Chicago, Illinois

Industry Presence in State – 807 FDA–regulated establishments

- Food establishments – includes cosmetics – 52 percent
- Medical device and Radiological establishments – 22 percent
- Animal drug and feed establishments – 12 percent
- Human drug establishments – 11 percent
- Biologic establishments – includes blood banks – 3 percent

Industry Highlights:

- One of the largest producers of generic drug tablets in the country.
- Aquaculture (seafood)
- Many small acidified food producers (cottage industries)

Contracts & Partnerships:

State Contracts

West Virginia Bureau of Public Health

- Conduct 80 inspections for food safety.
- Conduct inspections of mammography facilities.

West Virginia Department of Agriculture

- Conduct 45 inspections of warehouses and seafood processors for food safety.
- Monitor and perform inspections of 30 feed mills, renderers and others to assure compliance with BSE regulations.

State Partnerships

West Virginia Department of Agriculture

- Conduct inspections of fish farms and processors, collect samples and analyze for pesticide and industrial chemical residues

West Virginia Radiological Health Program

- Conduct inspections new and reassembled x–ray equipment

Fact Sheet – Wisconsin

FDA Presence:

- 40 Full Time employees in Wisconsin
- Resident Posts: Milwaukee, Madison, Green Bay, La Crosse and Stevens Point
  Report to: Minneapolis District, Minneapolis, Minnesota
  Reports to: Central Region, Chicago, Illinois

Industry Presence in State – 4,834 FDA–regulated establishments

- Food establishments – includes cosmetics – 57 percent
- Animal drug and feed establishments – 19 percent
- Medical device and Radiological establishments – 15 percent
- Human drug establishments – 7 percent
- Biologic establishments – includes blood banks – 2 percent

Imports:

- There are 3 ports of entry in the State of Wisconsin.
- FDA regulated import entries are primarily food, food additives, and medical devices.
- The Wisconsin FDA regulated import entries are handled out of the Minneapolis FDA office with assistance from the Madison Resident Post as needed.

Industry Highlights:

- Milk & Dairy – Leads the nation in total cheese, American cheese, Muenster cheese, Italian cheese, dry whey, and milk goat production; second in dairy cows, milk, butter, and mozzarella cheese.
- Cranberries – Ranks first in cranberry production.
- Low Acid Canned Foods – Ranks first in snap beans. Significant processing includes carrots, sweet corn, green peas, cucumbers/pickles, cabbage (kraut), and beets.
- Seafood – Home of more than 90 firms that process or handle seafood.
- Agriculture – Ranks first in corn for silage and oats production. Significant production occurs for: strawberries, maple syrup, mint for oil, potatoes, tart cherries, and ginseng.
- Medical Devices – Wisconsin is the home of 3 major medical device manufacturers: GE Medical Systems; General Electric Medical Systems Information Technology; & GE Imaging.

Contracts & Partnerships:

State Contracts

Wisconsin Department of Agriculture, Trade & Consumer Protection

- Conduct GMP inspections at licensed feed mills and BSE inspections at licensed and unlicensed feed facilities.
- Conduct food sanitation, seafood HACCP, and juice HACCP inspections.
- Conduct follow–up inspections of first time violators of tissue residues in food animals.

Wisconsin Department of Health and Social Services

- Conduct inspections of mammography facilities.

Fact Sheet – Wyoming

FDA Presence

- Wyoming is covered by the Denver District Office in Colorado. Denver District Office reports to Southwest Regional Office in Dallas, Texas
- Wyoming is the only state in the union without any permanently stationed FDA employees

Industry Presence in State – 304 FDA–regulated establishments

- Food establishments – includes cosmetics – 52 percent
- Human Drug establishments – 19 percent
- Medical Device and Radiological establishments – 14 percent
- Animal drug and feed establishments – 12 percent
- Biological establishments – includes blood banks – 3 percent

Industry Highlights

- Components of Wyoming's economy differ significantly from those of other states. The mineral extraction industry and the travel and tourism sector are the main drivers behind Wyoming's economy.
- Federal government owns 50% of its landmass, while 6% is controlled by the state.
- Wyoming's mineral commodities include coal, natural gas, coal bed methane, crude oil, and trona. Wyoming ranks highest in mining employment in the U.S.
- The main agricultural commodities produced in Wyoming include livestock (beef), hay, sugar beets, grain (wheat and barley), and wool. Over 91% of land in Wyoming is classified as rural.

Contracts, Partnerships & Local Activities

State Contracts

Wyoming Department of Agriculture

- Conduct 35 food sanitation inspections

Wyoming Department of Health

- Conduct inspections of mammography facilities.

State Partnerships

Wyoming Department of Agriculture

- Share oversight & authority of regulated dairy manufacturing facilities.

Wyoming State Board of Pharmacy

- Conduct inspections of medical gas manufacturing facilities and share reports with the Denver District Office.

Glossary

	Glossary of Acronyms
AAFSC	Aquatic and Aquaculture Food Safety Training Center
ACOMS	Advisory Committee Oversight and Management Staff
ACSI	American Customer Satisfaction Index
ADA	American's with Disabilities Act
ADA	American Diabetes Association
ADUFA	Animal Drugs User Fee Act
AF	Acidified Food
AFRPS	Animal Feeds Regulatory Program Standards
AGDUFA	Animal Generic Drug User Fee Act
ALM	Automated Laboratory Management
ALS	Amyotrophic Lateral Sclerosis
AMP	Real Property Asset Management Plan
ANADA	Abbreviated New Animal Drug Application
ANDA	Abbreviated New Drug Application
APCHO	Asian and Pacific Community Health Organizations
APDS	Artificial Pancreas Device Systems
APEC	Asia-Pacific Economic Cooperation
APHIS	Animal and Plant Health Inspection Service
APHL	Association of Public Health Laboratories
API	Active Pharmaceutical Ingredient
AQSIQ	Administration of Quality Supervision, Inspection and Quarantine
ARL	Arkansas Regional Laboratory
ASPR	Assistant Secretary for Preparedness and Response
AV	Audio Visual
BA	Budget Authority
BACPAK	bacterial-pathogen knowledgebase
BAM	Bacteriological Analytical Manual
BARDA	Biomedical Advanced Research and Development Authority
BEQ	Bioequivalence
BIMO	Bioresearch Monitoring
BLA	Biologics License Application
Blood SCAN	Blood Safety Continuous Active-Surveillance Network
BMAR	Backlog of Maintenance and Repairs
BPA	Bisphenol A
BPA	Business Process Automation
BPCA	Best Pharmaceuticals for Children Act

	Glossary of Acronyms
BRF	Beltsville Research Facility
BSE	Bovine Spongiform Encephalopathy
BSL	Biosafety Level
BsUFA	Biosimilar User Fee Act
CAP	Certificate Application Process
CBER	Center for Biologics Evaluation and Research
CBP	Customs and Border Protection
CBRN	Chemical, Biological, Radiological, and Nuclear
CDC	Centers for Disease Control and Prevention
CDER	Center for Drug Evaluation and Research
CDRH	Center for Devices and Radiological Health
CERSIs	Centers of Excellence in Regulatory Science and Innovation
CFIA	Canada Food Inspection Agency
CFR	Code of Federal Regulations
CFSAN	Center for Food Safety and Applied Nutrition
cGMP	Current Good Manufacturing Practice
cGMP	current Good Manufacturing Practice
CGTP	Current Good Tissue Practice
CII-FACE	Coalition of India Industry-Food and Agriculture Center of Excellence
CJD	Creutzfeldt-Jakob
CMS	Centers for Medicare and Medicaid Services
COMPACT	Compendium of Microbiological Protocols and Chemical Tests
CORE	Coordinated Outbreak Response and Evaluation
CORES	Collaborative Opportunities for Research Excellence in Science
COTS	Commercial Off-The-Shelf
CP	Citizen Petition
CRADA	Cooperative Research & Development Agreement
CT	Computed tomography
CTP	Center for Tobacco Products
CVM	Center for Veterinary Medicine
DARPA	Defense Advanced Research Projects Agency
DFDT	Division of Food Defense Targeting (formerly known as Prior Notice Center)
DHHS	Department of Health and Human Services
DHS	Department of Homeland Security
DIOP	Division of Import Operations and Policy

	Glossary of Acronyms
DMAA	Dimetnylamylamine
DNA	Deoxyribonucleic Acid
DNR	Domain Name Registrar
DOD	Department of Defense
DSP	Diarrhetic Shellfish Poisoning
DTC	Direct-To-Consumer
DWPE	Detention Without Physical Examination
ECG	Electrocardiogram
EDKB	Endocrine Disruptor Knowledge Base
EDSR	Electronic Document Submission and Review
EHEC	Enterohemorrhagic *E. Coli*
EIR	Entrepreneurs in Residence
eLEXNET	Electronic Laboratory Exchange Network
EMA	Economically Motivated Adulteration
EON	Emergency Operations Network (EON
EON IMS	Emergency Operations Network Incident Management System
EPA	Environmental Protection Agency
ER	Entry Review
ESRD	End-stage renal disease
eSub	Electronic Submissions
EU	European Union
EUA	Emergency Use Authorization
FACA	Federal Advisory Committee Act
FACTS	Field Accomplishments and Compliance Tracking System
FCC	Forensic Chemistry Center
FCI	Facility Condition Index
FCN	Food Contact Notification
FCS	Food Contact Substances
FD&C Act	Food Drug and Cosmetic Act
FDA	Food and Drug Administration
FDA	Food and Drug Administration
FDA EOP	FDA Emergency Operations Plan
FDAAA	Food and Drug Administration Amendments Act of 2007
FDAMA	Food and Drug Administration Modernization Act of 1997
FDASIA	FDA Safety and Innovation Act
FDA-TRACK	FDA Transparency Results Accountability Credibility Knowledge

	Glossary of Acronyms
FDCA	Federal Food, Drug, and Cosmetic Act
FEMP	Federal Energy Management Program
FERN	Food Emergency Response Network
FFDCA	Federal Food, Drug & Cosmetic Act
FMLS	Firms Master List Services
FOIA	Freedom of Information Act
FSMA	Food Safety Modernization Act
FSPCA	Food Safety Preventive Controls Alliance
FSPTCA	Family Smoking Prevention and Tobacco Contract Act (Tobacco Control Act)
FSVP	Foreign Supplier Verification Program
FTE	Full Time Equivalent
FURLS	FDA Unified Registration and Listing Systems
FVM	Food and Veterinary Medicine
FY	Fiscal Year
GAO	Government Accountability Office
GCP	Good Clinical Practices
GDUFA	Generic Drug User Fee Amendments of 2012
GIS	Geographic Information System
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
GOTS	Government off-the-shelf software
GSA	General Services Administration
GSRS	Global Summit on Regulatory Science
HACCP	Hazard Analysis and Critical Control Point
HBV	Hepatitis B Virus
HC	Health Canada
HCT/P	Human Cells, Tissues and Cellular and Tissue-Based Product
HCV	Hepatitis C Virus
HHS	Department of Health and Human Services
HIV	Human Immunodeficiency Virus
HPHC	harmful and potentially harmful tobacco product constituent
HRSA	Health Resources and Services Administration
HSP	Human Subject Protection
HTLV	Human T-Lymphotropic Virus
HUD	Humanitarian Use Device

	Glossary of Acronyms
HVAC	Heating, Ventilation, and Air Conditioning
ICA	Incident Command Alert
ICCR	International Cooperation on Cosmetics Regulation
ICH	International Conference on Harmonization
ICS	Incident Command Center
ICU	Intensive Care Unit
IDE	Investigational Device Exemption
IFSS	Integrated Food Safety System
IIT IFSH	Illinois Institute of Technology Institute for Food Safety and Health
IIWA	International Internet Week of Action
IJPA	International Jelly and Preserve Association
IND	Investigational New Drug
INDA	Investigational New Drug Application
INTERPOL	International Criminal Police Organization
IPT	International Programs Team
IRB	Institutional Review Board
iRISK	FDA's comparative risk assessment tool
ISO	International Organization for Standardization
ISP	Internat Service Provider
IT	Information Technology
ITACS	Import Trade Auxiliary Communications System
JIFSAN	Joint Institute for Food Safety and Applied Nutrition
JLC	Jefferson Laboratories Complex
LACF	Low-Acid Canned Food
LDL	Low-density Lipoprotein
LIMS	Laboratory Information Management System
LLNL	Lawrence Livermore National Laboratory
LTKB	Liver Toxicity Knowledge Base
MAQC	MicroArray Quality Control
MARCS	Mission Accomplishment and Regulatory Compliance Services
MCMi	Medical Countermeasures initiative
MDIC	Medical Device Innovation Consortium
MDR	Medical Device Reporting
MDSAP	Medical Device Single Audit Program

	Glossary of Acronyms
MDUFA	Medical Device User Fee Amendments
MDUFMA	Medical Device User Fee and Modernization Act
MFAEAR	Mammography Facility Adverse Event and Action Report
MFRPS	Manufactured Food Regulatory Program Standards
MFRPS	Manufactured Foods Regulatory Program Standards
MIN-DO	Minneapolis District Office
MOD	Module
MOU	Memorandum of Understanding
MQSA	Mammography Quality Standards Act
MR	Magnetic Resonance
MRC	Muirkirk Road Complex
MRI	Magnetic Resonanceimaging
MRS	Magnetic Resonance Spectroscopy
MS	Multiple Sclerosis
NACDS	National Association of Chain Drug Stores
NADA	New Animal Drug Application
NARMS	National Antimicrobial Resistance Monitoring System
NATS	National Adult Tobacco Survey
NCAPIP	National Council of Asian and Pacific Islander Physicians
NCATS	National Center for Advancing Translational Science
NCBI	National Center for Biotechnology Information
NCI	National Cancer Institute
NCSP	National Check Sample Program
NCTR	National Center for Toxicological Research
NDA	New Drug Application
NGS	Next-Generation Sequencing
NICBR	National Interagency Confederation for Biological Research
NIH	National Institutes of Health
NIMS	National Incident Management System
NMFS	National Marine Fisheries Service
NSE	Not Substantially Equivalent
NYTS	National Youth Tobacco Survey
OASIS	Operational and Administrative System for Import Support
OCC	Office of the Chief Counsel
OCE	Office of Compliance and Enforcement
OCET	Office of Counterterrorism and Emerging Threats

	Glossary of Acronyms
OCI	Office of Criminal Investigations
OCM	Office of Crisis Management
OCP	Office of Combination Products
OCS	Office of the Chief Scientist
OCTC	Office of the Counselor to the Commissioner
OCTGT	Office of Cellular, Tissue and Gene Therapies
OD	Office of the Center Director
OEA	Office of External Affairs
OER	Office of External Relations
OFVM	Office of Foods and Veterinary Medicine
OGCP	Office of Good Clinical Practice
OGROP	Office of Global Regulatory Operations and Policy
OHCE	Office of Health Communication and Education
OIP	Office of International Programs
OL	Office of Legislation
OM	Office of Management
OMB	Office of Management and Budget
OMH	Office of Minority Health
OMPT	Office of Medical Products and Tobacco
OOPD	Office of Orphan Products Development
OP	Office of Policy
OPA	Office of Public Affairs
OPAS	Online Program Analysis System
OPP	Office of Policy and Planning
OPT	Office of Pediatric Therapeutics
OR	Office of Regulations
ORA	Office of Regulatory Affairs
ORADSS	Online Reporting Analysis Decision Support System
ORISE	Oak Ridge Institute for Science and Education
ORSI	Office of Regulatory Science and Innovation
OS	Office of Science
OSCS	Oversulfated Chondroitin Sulfate
OSHI	Office of Special Health Issues
OSI	Office of Scientific Integrity
OSMP	Office of Special Medical Programs
OSPD	Office of Scientific and Professional Development
OTC	Over-The-Counter
OWH	Office of Women’s Health

	Glossary of Acronyms
PAC	Pediatric Advisory Committee
PAS	Post- Approval Studies
PATH	Population Assessment of Tobacco and Health
PCR	Polymerase Chain Reaction
PDC	Pediatric Device Consortia
PDMA	Prescription Drug Marketing Act
PDUFA	Prescription Drug User Fee Act
PET	Positron Emission Topography
PETNet	Pet Event Tracking Network
PFGE	Pulsed Field Gel Electrophoresis
PFR	Pet Food Report
PGx	Pharmacogenomics
PHEMCE	Public Health and Emergency Countermeasures Enterprise
PIC/S	Pharmaceutical Inspection Convention and Cooperation Scheme
PMA	Premarket Approval Application
PPD	Presidential Policy Directives
PPP	Public Private Partnerships
PREA	Pediatric Research Equity Act
PREDICT	Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting
PRISM	Post-Licensure Rapid Immunization Safety Monitoring
PRV	Priority Review Voucher
PST	Paralytic Shellfish Toxin
QMiS	Quality Management Information Systems
QPRAM	Quantitative Predictive Risk Assessment Model
QSIT	Quality System Inspection Technique
RBIS	Regulatory Business Information Services
REMS	Risk Evaluation Mitigation Strategies
RFR	Reportable Food Registry
RNA	Ribonucleic Acid
RPS	Regulated Product Submissions
RRT	Rapid Response Team
SE	*Salmonella* Enteritidis
SEQC	Sequencing Quality Control

	Glossary of Acronyms
SMG	Staff Manual Guide
SMSHA	Substance Abuse and Mental Health Services Administration
SNS	Strategic National Stockpile
SRL	Southeast Regional Laboratory (ORA)
SRMS	Stakeholder Relationship Management System
TAVR	Transcatheter Aortic Valve Replacement
TCA	Family Smoking Prevention and Tobacco Contract Act (Tobacco Control Act)
TIMS	Tobacco Inspection Management Systems
TPMP	Tobacco Product Manufacturing Practice
TPSAC	Tobacco Product Scientific Advisory Committee
UAMS	University of Arkansas for Medical Sciences
UAT	User Acceptance Testing
UC	UC Davis Western Center for Food Safety
UDI	Unique Device Identification
UDID	Unique Device Identification Database
UESC	Utility Energy Service Contract
UF	User Fee
UFI	Unique Facility Identifier
UN	United Nations
USDA	United States Department of Agriculture
USP	United Stated Pharmacopeia
UTMB	University of Texas Medical Branch
VA	Veterans Administration
VAERS	Vaccine Adverse Event Reporting System
Vet-LIRN	Veterinary-Laboratory Investigation and Response Network
Vet-LRN	Veterinary-Laboratory Response Network
VICH	Veterinary International Conference on Harmonization
VQIP	Voluntary Qualified Importer Program
WEAC	Winchester Engineering and Analytical Center
WGS	Whole Genome Sequencing
WHO	World Health Organization